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Guidance for the Reregistration of Pesticide Products Containing Maneb as the Active Ingredient

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Guidance for the Reregistration of Pesticide Products Containing MANEB as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

MANEB
AS THE ACTIVE INGREDIENT

CASE NUMBER 0642

CAS (DOCKET) NUMBER 12427-38-2

EPA CHEMICAL CODE: 014505

OCTOBER 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

TABLE OF CONTENTS

Glossary of Terms and Abbreviations

I. Introduction 1

II. Chemical(s) Covered by this Standard 4
- A. Description of Chemical
- B. Use Profile
- C. Background

III. Agency Assessment 11
- A. Summary
- B. Preliminary Risk Assessment
- C. Other Science Findings
- D. Tolerance Reassessment

IV. Regulatory Position and Rationale. 40
- A. Regulatory Positions
- B. Criteria for Registration
- C. Acceptable Ranges and Limits
- D. Required Labeling

V. Products Subject to this Standard 50

VI. Requirement for Submission of Generic Data 52
- A. What are Generic Data?
- B. Who must Submit Generic Data?
- C. What Generic Data must be Submitted?
- D. How to Comply with DCI Requirements
- E. Registrants Requests Regarding Data Requirements and Agency Response
- F. Test Protocol and Standards
- G. Procedures for Requesting a Change in Test Protocol
- H. Procedures for Requesting Extensions of Time
- I. Data Format and Reporting Requirements
- J. Existing Stocks Provisions upon Suspension or Cancellation

VII. Requirement for Submission of Product-Specific Data 58

VIII. Requirement for Submission of Revised Labeling . . . 59

IX. Instructions for Submission. 59
- A. Manufacturing use products (sole active)
- B. Manufacturing use products (multiple active)
- C. End-Use Products (sole active)
- D. End-Use Products Containing the Subject Active Ingredient as One of Multiple Active Ingredients
- E. Intrastate products

APPENDICES

I. DATA APPENDICES 64

- Guide to Tables
- Table A
- Table B

II. LABELING APPENDICES 120

- Summary of label requirements and table
- 40 CFR 156.10 Labeling Requirements
- Physical/Chemical Hazards Labeling Statements
- Storage Instructions
- Pesticide Disposal Instructions
- Container Disposal Instructions

III. BIBLIOGRAPHY APPENDICES 145

- Guide to Bibliography
- Bibliography

IV. FORMS APPENDICES 155

- EPA Form 8580-1 FIFRA §3(c)(2)(B) Summary Sheet
- EPA Form 8580-3 Generic Data Exemption Statement
- EPA Form 8580-4 Product Specific Data Report
- EPA Form 8580-6 Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data

GLOSSARY OF TERMS AND ABBREVIATIONS

The following terms are used throughout this Registration Standard and are defined here for the convenience of the reader.

ADI: (Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a complete data base.

ai: Active ingredient

CAS: Chemical Abstract Service (number)

Core Classification: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline)

EEC: (Estimated Environmental Concentration) Estimated pesticide concentration in the environment (terrestrial or aquatic ecosystem).

EP: End-use Product

EPA: The Environmental Protection Agency, also "the Agency"

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

HDT: Highest dose tested

Invalid: Studies which are deficient in some vital parameter or those studies which have been judged not to be scientifically sound or those studies whose reliability is seriously questioned.

LC_{50}: (median lethal concentration): a statistically derived concentration of a substance that can be expected to cause death in 50 percent of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/L or ppm).

LD_{50}: (median lethal dose): a statistically derived single dose that can be expected to cause death in 50 percent of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

MOS: Margin of Safety - The calculation of a margin of safety involves division of an appropriate NOEL by a worker's estimated exposure. The result is a unitless figure which gives an indication of how close a worker's internal dose is in relation to the NOEL for laboratory animals.

MPI: Maximum Permissible Intake

MRID: Master Record Identification (number)--EPA's system of tracking studies used in support of registrations

MP: Manufacturing-use product

NPDES: National Pollutant Discharge Elimination System

NOEL: No Observed Effect Level--the maximum dose used in a test which produces no observed adverse effects.

OPP: The Office of Pesticide Programs (EPA)

OM: Organic matter (used to describe soils)

ppm: Parts per million

PADI: (Provisional Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a limited data base.

PAI: Pure active ingredient

Technical: Active ingredient as manufactured

TMRC: (Theoretical Maximum Residue Contribution) An estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figures for each crop. TMRC is usually expressed in terms of mg ai/day, assuming a 60 kg person.

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring the product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review and use index, which are not contained in this document, but are available upon request[1], focus on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end-use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end-use products if necessary to protect man and the environment.

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[1] The scientific reviews and use index are available from the National Technical information Service, 5285 Port Royal Road, Springfield, Va. 22161 or from Order Desk (703) 487-4650.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with the data submission requirements may result in issuance of a Notice of Intent to Suspend. Failure to comply with the other requirements in this Standard may result in issuance of a Notice of Intent to Cancel.

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a Special Review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A and B in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL(S) COVERED BY THIS STANDARD

A. Description of chemical(s)

The following chemical(s) are covered by this Registration Standard:

Common name: Maneb

Chemical name: Manganese ethylene bisdithiocarbamate

CAS Number: 12427-38-2

OPP (Shaughnessy) Numbers: 014505

Empirical Formula: $(C_4H_6MnN_2S_4)x$

Trade names: Dithane® M-22, Manzate®, Manex®

Description of physical characteristics of chemical
Color: Yellow
Physical State: Powder
Odor: Faint

B. Use Profile

Type of Pesticide: Fungicide

Pests Controlled (in general): Foliar fungal diseases of selected fruit, nut, vegetable, grain, field and ornamental (including turf) crops.

Registered Uses: Terrestrial food crop use on fruit (apple, apricot, banana, caprifig, cranberry, fig (Kadota), grapes, nectarine, papaya, peach, pineapple (progagation stock)), nuts (almonds and peanuts), vegetables (asparagus (including plant stock), beans (including dried-type, succulent, lima beans, blackeyed peas and cowpeas), broccoli, Brussels sprouts, cauliflower, cabbage, carrots, celery, Chinese cabbage, collards, corn (field, pop, sweet), cucumber, eggplant, endive, kale, kohlrabi, lettuce, melons (cantaloupe, casaba melons, crenshaw melons, honeydew melons, muskmelons, Persian melons, and watermelons), onion, peppers, potatoes (including seed pieces), pumpkins, spinach, squash (summer and winter), sugar beets, tomato, turnips, and agricultural seed treatment (barley, beans, peas, corn, cotton, flax, oats, peanuts, rice, rye, safflower, sorghum, soybeans, sugar beets, sunflower, wheat); Terrestrial nonfood crop use on tobacco and ornamental flowering plants, shrubs, shade trees, and grasses (seed crop) and turf; Greenhouse food crop use on rhubarb and tomato; Greenhouse nonfood crop use on Epcot display crops.

Predominant Use(s): The major use sites are potatoes, tomatoes, apples and sweet corn.

Mode of Activity: Inhibition of certain fungal enzyme systems

Formulation Types Registered: Technical (85%, 86%, 90%) and
Formulation Intermediate (80%) maneb
End-Use Products - dusts,
granulars, wettable powders,
wettable powder/dusts
flowable concentrates,
and ready-to-use formulations

Method(s) of Application: The major volume of use for maneb is for foliar application to vegetable crops and apples. Spray application of maneb to foliage of all crops for which it is registered may be accomplished by aerial equipment as well as by ground equipment. For ground equipment, maneb suspensions typically are made from a wettable or flowable powder that would be applied by means of air blast sprayers or by means of tractor mounted boom sprayers. For application of dust formulations, maneb would be applied by means of truck or tractor drawn duster or aerial equipment. For foliar treatment of tobacco or vegetable seed beds, application of sprays or dusts might be by means of hand-held compressed air sprayers or dusting equipment. Potato and tomato foliage may be treated by means of solid set, wheel move, or center pivot sprinkler irrigation equipment.

Application Rates: Terrestrial food crop: 0.01 - 8.4 lb ai/A
Terrestrial nonfood crop: 0.8 - 3.2 lb ai/A
Greenhouse food crop: 1.1 - 2.4 lb ai/100 gal
Greenhouse nonfood crop: 0.8 - 2.4 lb ai/100 gal

C. Background

Maneb is one of six chemicals classified as ethylene bisdithiocarbamate (EBDC) fungicides. These broad spectrum fungicides are used to prevent crop damage by fungi and to protect harvested products from deterioration. The chemical structure of maneb and the other EBDC's (amobam, metiram, nabam, mancozeb, and zineb) and their metabolite, ethylenethiourea (ETU), are depicted in Table 1.

The chemistry of the EBDC's is complicated by their instability and their propensity to form polymers. The solubilities of several of the EBDC's in water and other solvents vary from insoluble to completely soluble. The EBDC's are generally unstable in the presence of moisture and oxygen, as well as in biological systems. A common contaminant, degradation product, and metabolite of all EBDC's is ETU, an odorless white crystalline solid that is soluble in water but insoluble in common organic solvents. EBDC residues in or on foods are known to convert readily to ETU during commercial processing or home cooking.

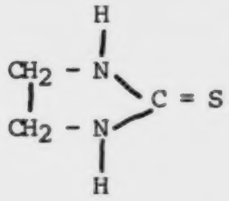
In 1977, the Agency initiated a Special Review (formerly referred to as Rebuttable Presumption Against Registration [RPAR]) of the EBDC's. The Special Review process is designed to help the Agency determine whether to initiate procedures to cancel, deny or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment, in accordance with sections 3(c)(6) and 6 of FIFRA. This process is set forth in 40 CFR 154, which describes various risk criteria and provides that a Special Review may arise if the Agency determines that any of these criteria have been met.

The EBDC Special Review was based on the presumption that the EBDC's, and the metabolite ETU, posed three kinds of risk to human health or the environment: oncogenicity, teratogenicity, and acute toxicity to aquatic organisms. Three additional areas of concern were also identified: thyroid toxicity, mutagenicity, and skin sensitization. Skin sensitization was subsequently determined not to meet a Special Review criterion.

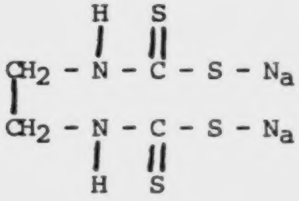
TABLE 1

CHEMICAL STRUCTURE OF EBDC'S AND ETU

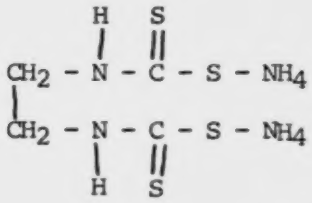
ETHYLENE THIOUREA (ETU)



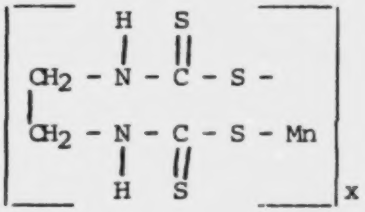
NABAM



AMOBAM

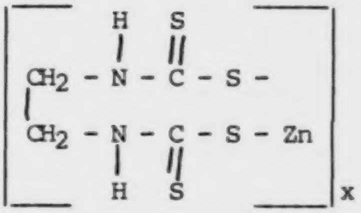


MANEB



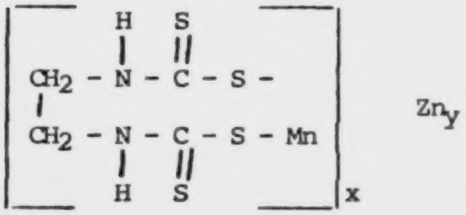
x > 1

ZINEB

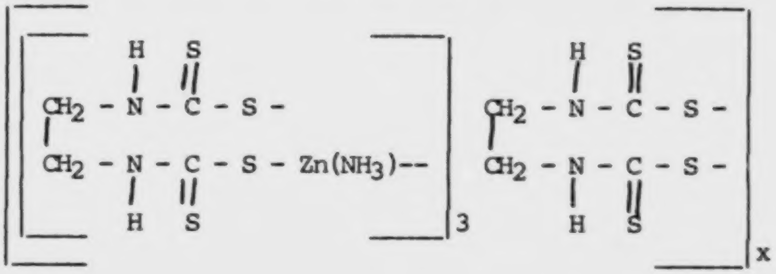


x > 1

MANCOZEB



METIRAM



x > 1

The Agency evaluated these potential risks in depth, taking into account uncertainties associated with the risk estimates, considering the significant benefits of the EBDC's and weighing various regulatory options. In 1982, the Agency issued its Decision Document on all EBDC's reporting on the results of the evaluation. This evaluation resulted in the following conclusions.

1. The potential risk of acute toxicity to aquatic organisms resulting from use of mancozeb on commercially grown wild rice would be mitigated through present cultivating practices and the addition of a statement to the label warning users of a hazard to fish.

2. Potential risks of teratogenicity and thyroid toxicity to commercial and agricultural applicators would be adequately reduced by requiring protective clothing.

3. Potential dietary exposure resulting from consumption of home grown produce could be reduced by highlighting preharvest intervals on labels of noncommercial (home use) products used by home gardeners.

4. The issues of whether EBDC's or ETU pose a potential risk of oncogenicity, mutagenicity, teratogenicity, and thyroid effects to man were subject to many uncertainties. Available data on oncogenicity and mutagenicity were not adequate to resolve key scientific issues such as the mechanism of action of EBDC's and ETU. Additional data on the EBDC's and ETU were needed for the Agency to determine their mutagenic potential and to assess human exposure and oncogenic risk. Some data would be required at termination of the Special Review while further data needs, with particular emphasis on chronic studies, dietary residues and exposure, would be identified during a later reregistration review. Data needs identified at that time included:

    a. Metabolism studies designed to define the *in vivo* conversion of the various EBDC's to ETU and other metabolites.

    b. Dermal absorption studies designed to demonstrate the dermal penetration of each of the EBDC's and ETU.

    c. Five mutagenicity studies on each of the six registered EBDC's.

    d. Mammalian cell transformation assays on each of the six EBDC's and ETU.

With the issuance of the Decision Document, the Agency concluded the Special Review and returned the EBDC's to the registration process on the condition that registrants comply with the label changes and data requirements specified in the Decision

Document.

Since issuance of the Decision Document, the Agency has issued eight data call-in notices for maneb as follows:

1. January 17, 1983: This notice required the submission of the metabolism, dermal penetration and mutagenicity data identified in the 1982 Decision Document.

2. July 25, 1984: This notice advised registrants of the Agency's concern about the existence of pesticides in ground water and the designation of a number of chemicals, including maneb, which may have the potential to contaminate ground water. The chemicals were designated based on such factors as chemical structure, solubility, and use patterns. The notice required submission of certain environmental fate and product chemistry data for the agricultural uses only.

3. October 19, 1984: This notice required dietary exposure, product chemistry and toxicological (subchronic feeding and inhalation) data considered necessary to reassess the registration status of maneb.

4. March 20, 1985: This notice required registrants of pesticide products containing maneb to submit all outstanding data requirements as outlined under 40 CFR 158 regulations for disciplines including product chemistry, toxicology, wildlife and aquatic organisms, and environmental fate.

5. April 30, 1985: This notice required additional data, not identified in the October 1984 call-in notice, but considered necessary to the reassessment of the chemicals. These data were additional toxicological (subchronic feeding and inhalation - ETU) and residue data for ETU as well as maneb.

6. March 31, 1987: Residue chemistry data were required in the October 19, 1984 Data Call In Notice. Because adequate storage stability data were not submitted to ascertain whether residues of maneb and/or ETU are stable in or on plant commodities when stored, firm conclusions on dietary exposure to maneb or ETU from the use of maneb could not be drawn based on data available at that time. Therefore, this DCI required storage stability data and crop residue data for maneb and ETU.

7. April 1, 1987: This notice required additional data necessary to support the continued registration of maneb. These data requirements pertain in general to the comprehensive review of the chemical which included the reassessment of tolerances. These data included environmental fate, product chemistry, residue chemistry, toxicology,

and wildlife and aquatic organisms studies.

8. April 25, 1988: The Notice required a small-scale retrospective ground water monitoring study. Results of previous studies indicated that maneb/ETU and/or its degradate(s) have the potential to leach into ground water. The Agency decided that additional data were needed to define further the extent of the ground water problem.

The data required by the first five call-in notices to support the continued registration of maneb products have been received and considered by the Agency in its evaluation of maneb, as presented in the assessment section of this Standard. Data submitted in response to the March 31, 1987, April 1, 1987 and April 25, 1988 Data Call In Notices were not due in time to be reviewed and included in this Standard. However, all maneb data submitted are being reviewed and the registrant(s) will be informed as to the results of the Agency review when completed.

In June 1987, the Agency initiated another Special Review for the EBDC's because of concern about the oncogenic risk to consumers from dietary exposure to ETU from foods treated with these pesticides, and the risks of teratogenicity and adverse thyroid effects to applicators and mixer/loaders from exposure to ETU. ETU is present as part of the residue of the EBDC pesticides on or in treated agricultural commodities. In addition, a portion of the EBDC pesticide residues convert into ETU in the body after ingestion. At the time of initiating the Special Review, the Agency estimated that the lifetime dietary oncogenic risk to consumers from these two sources of exposure to ETU was 2.2×10^{-5}. This estimate is based on exposure to ETU from the residues of only one of the EBDC pesticides, mancozeb. Consequently, the overall dietary risk may be higher due to contributions from the other EBDC's.

III. AGENCY ASSESSMENT

A. SUMMARY

Based on the review of available data, the Agency has reached the conclusions set forth in this Standard. A summary of those conclusions follows. A more detailed discussion is contained in the remainder of this Chapter.

1. A major toxicological concern from exposure to maneb is the hazard to the human thyroid from ethylenethiourea (ETU), a contaminant, degradation product, and metabolite present in maneb and other EBDC products. Additional chronic studies on maneb are required for further evaluation.
2. ETU has caused developmentally toxic/teratogenic effects in rats and hamsters. There are no adequate teratology studies on maneb. Teratology studies with maneb are required before its teratogenicity can be fully assessed.
3. ETU has been classified as a Group B2 oncogen in accordance with the Agency's Guidelines for Carcinogen Risk Assessment (September 26, 1986, 51 CFR 33992), based on studies which show that it induced an increased incidence of thyroid adenomas and adenocarcinomas in rats and hepatomas in mice.
4. In June 1987, the Agency initiated a Special Review for the EBDC's because of concern about the oncogenic risk to consumers from dietary exposure to ETU from foods treated with these pesticides, and the risks of teratogenicity and adverse thyroid effects to applicators and mixer/loaders from exposure to ETU.

As a result of this review, the Agency has identified missing data needed to further evaluate the environmental and human risks associated with the use of maneb. These data must be submitted in order to maintain registrations of products or register new products containing maneb. Almost all of these data have been required in previous Data Call-In Notices. Details can be obtained by referring to the tables in Appendix I.

The Agency has also determined that certain label restrictions or revisions are necessary in order for maneb products to remain in compliance with FIFRA, as indicated below. Chapter IV, Section D, Labeling, contains the specific wording for each of the labeling statements and identifies the products to which each labeling statement applies.

- Protective clothing requirements
- Environmental hazard precautions
- Reentry interval
- Worker safety rules
- Preharvest interval emphasis
- Grazing Restrictions

The Regulatory Position and Rationale section discusses the Agency's position regarding maneb.

B. PRELIMINARY RISK ASSESSMENT

Toxicology Studies - Maneb. In its review of maneb, the Agency has considered the available data as summarized below:

1. Acute Toxicity and Irritation Studies. The acute studies are adequate to fulfill the data requirements. Maneb (80%) does not appear to be acutely toxic (Toxicity Category III or IV, except for eye irritation, Toxicity Category II). An acute oral study on "Technical Maneb" (% not given) showed it to be of lesser toxicity than the 80% compound.

2. Subchronic Testing

Oral (Rodent, Nonrodent) Studies. The nonrodent study submitted in response to the Data Call In Notice of October 19, 1984, is acceptable. Although there is no adequate rodent feeding study, this will not be required if additional information is submitted on the 31-month rat feeding study.

Monkeys were fed 0, 100, 300 or 3000 ppm (0, 5, 15, 150 mg/kg/day) of technical maneb for 6 months. There was no mortality at any dose level; the NOEL was 100 ppm (5 mg/kg/day), and the LEL (increase in thyroid weight in males) was 300 ppm (15 mg/kg/day). Effects at 3000 ppm (150 mg/kg/day) were an increase in mean thyroid weight associated with an enlargement of this organ, along with significantly reduced ^{131}I absorption in the thyroid, and lower mean percentage of protein-bound ^{131}I at 26 weeks. Males at 3000 ppm (150 mg/kg/day) showed reduced weight gains and somewhat lower food consumption relative to their controls. This study satisfies the data requirement for a 90-day nonrodent feeding study.

In an unpublished study conducted on a "Manzate" formulation of manganese ethylenebisdithiocarbamate, groups of weanling rats are reported as having been fed 0, 100, 1,000 or 10,000 ppm (0, 5, 50, 500 mg/kg/day) "active ingredient" for 97 days. At 10,000 ppm (500 mg/kg/day) there was considerable reduction in mean body weight, and there was only 40% survival to termination in male rats. An autopsy revealed "general emaciation of the organs, exophthalmos, and extensive hyperplasia of the thyroid." There was no mortality at 1,000 ppm (50 mg/kg/day); male rats at this level showed no effects, but 80% of females had some degree of thyroid hyperplasia. No effects were observed at 100 ppm (5 mg/kg/day). Because of a number of deficiencies (including, but not limited to, an insufficient number of animals/group and lack of analytical data for maneb and/or ETU) this particular study has been classified as supplementary data. The requirement for a subchronic rodent feeding study has not been satisfied. However, since a chronic rodent study is required, further subchronic studies in rodents will not be necessary.

Dermal Studies - No data were available for the evaluation of the subchronic dermal effects. Based on the use patterns, a 21-day dermal toxicity study is required.

Subchronic Inhalation - A 90-day subchronic inhalation study on technical maneb was conducted on groups of Sprague-Dawley derived rats. The animals were exposed 6 hours/day, 5 days a week for 13 consecutive weeks to gravimetrically determined concentrations of 0, 10, 32 or 98 mg/m^3 of technical maneb.

There were statistically significant reduced mean body weights at 13 weeks in females which had been exposed to 32 and 98 mg/m^3. Males exposed to 98 mg/m^3 consistently had lower mean body weights than their controls through week 13, but this was statistically significant only at 1, 2 and 3 weeks.

Chorioretinal hypoplasia occurred (at low incidence) only in rats exposed to 32 and 98 mg/m^3, while ophthalmological keratitis was present (at an incidence of 5%) only in rats exposed to 98 mg/m^3.

No dose-related effects were observed in the histopathologic examination conducted on rats sacrificed at 13 weeks.

The major value of this study is that it provides some ETU thyroid residue data at the highest exposure level. Paradoxically, it was the high-dose males which showed the higher levels of ETU residue associated with the thyroid (23.6 mcg/ml versus 8.4 mcg/ml for females), while females showed possible (but not statistically significant) decreases in two thyroid hormones T_3 (triiodothyronine) and T_4 (tetraiodothyronine).

This study is currently classified as supplementary, partly because the toxic effects observed at the highest concentration (98 mg/m^3) of maneb tested were such that the question exists as to whether this is a maximally tolerated dose or is sufficiently close to it. There was some mortality in a preliminary 5-day study at 290 mg/m^3, but that level is more than twice 98 mg/m^3, highest concentration in the 90-day study.

An additional concern is that no residue data for ETU and/or maneb were obtained for lung tissue. Also, manganese by inhalation is a potential hazard, as humans exposed to manganese salts or ores by this route may develop symptoms similar to those of Parkinsonism. For this reason, some analytical determination of manganese in the lung tissue of exposed rats is appropriate. However, these analyses could be done on rats exposed for considerably less than 90 days.

Histopathology data from rats sacrificed after a 13-week recovery period and analytical data for lung tissue are required to upgrade the existing study.

3. Chronic Testing

Chronic Toxicity Studies. In a two year study, CFW albino rats received 0, 25, 250 or 2500 ppm (0, 1.25, 12.5 and 125 mg/kg/day) of the active ingredient in their diet. An additional group was fed 1250 ppm (62.5 mg/kg/day) for a period of 97 days, and some of the rats were then sacrified. At 97 days, the mean thyroid weight for 1250 ppm (62.5 mg/kg/day) rats was significantly elevated, along with a reduction in growth rate as compared to controls.

In rats sacrificed at one year, the goitrogenic effect was evident as a significant increase in the weight of the thyroid in rats fed 2500 ppm (125 mg/kg/day) maneb, with females at 250 ppm showing a smaller increase in thyroid weight. Rats fed lower levels were unaffected.

Twenty-one of forty rats receiving 2500 ppm (125 mg/kg/day) maneb for one to two years developed nodular goiter, and four of these twenty-one also had well-developed thyroid adenomas. No nodular goiters were observed in rats receiving 0, 25, or 250 ppm (0, 1.25, 12.5 mg/kg/day) maneb for 1-2 years, although there were three occurrences of small thyroid adenomas.

The NOEL in this study was 250 ppm (12.5 mg/kg/day). The classification of this study is supplementary, because of an insufficient number of animals at each dosage level (after the one-year sacrifice there were 20 rats/sex/group) and lack of individual necropsy data.

In a second rat feeding study, groups of 90 male and 90 female Sprague-Dawley rats were fed technical maneb at concentrations of 0, 30, 100, 300 and 1000 ppm (0, 1.5, 5, 15, 50 mg/kg/day) for 31 months. There were interim sacrifices at 3, 6 and 12 months.

In a sampling of rats, there were statistically significant increases in the half-life for ^{131}I retention at 1000 ppm

(50 mg/kg/day). Additionally, there were elevated ^{131}I retention times at 12 and 24 months in 1000 ppm (50 mg/kg/day) females, and in 1000 ppm (50 mg/kg/day) males at 24 months.

There were indications of effects (decrease in mean body weight, increase in mean absolute thyroid weight, an increased incidence of bladder epithelial dysplasia in males only) in rats at 1000 ppm (50 mg/kg/day). However, this 31-month rat feeding study is classified as supplementary, with the possibility that it can be upgraded with additional data and some clarifications concerning the analysis of the diet fed to the rats.

In a one-year dog feeding study, doses of 0, 2, 20, 75 and 200 mg/kg/day of technical maneb were administered by capsule to groups of 2 male dogs. Muscular weakness of the hind legs occurred in all dogs at the two highest dose levels; the report notes that this was possibly induced by the manganese in the formulation.

The study stated that "Microscopic examination of the brain, spinal cord and peripheral nerves disclosed pathologic lesions of a degenerative nature in both control and test animals."

Muscle sections from dogs at 200 mg/kg/day and from one dog of the 75 mg/kg/day group showed striking degeneration or myopathy.

Dogs at 200 mg/kg/day showed a weight loss, and one of these animals, with severe signs of toxicity, was sacrificed after 57 doses of the test material and a 15-day recovery period. Clinical signs in both dogs at 200 mg/kg/day included loss of appetite, yellowish-orange feces, unkempt appearance, salivation, involuntary and excessive urination, muco-purulent nasal discharge, vomiting, fetid breath, signs of abdominal discomfort, cold extremities, tremors and posterior weakness progressing to flaccid paralysis of the hindquarters.

Despite a statement in the text of the report that there were no goitrogenic effects at any level, it is noteworthy that both dogs at 75 mg/kg/day were reported as having a heavier than usual thyroid, and in the dog at 200 mg/kg, which was treated with 202 doses before sacrifice, there were thyroid findings suggestive of hyperplasia.

This study indicates that maneb may cause neurologic toxicity at levels for which thyroid effects may not occur. This neurologic toxicity is not to be confused with the delayed neurotoxic effect of some organophosphates.

This study is classified as supplementary (reasons include but are not limited to, the low number of dogs per dosage group (2), use of only males and animals older than 9 months at initiation of the study). The classification of this study cannot be upgraded.

A one-year feeding study on a nonrodent (preferably the dog) is required. Additional information on the analysis of the diet fed to the rats is required for the rodent 31-month study before it is upgraded.

Oncogenicity Studies - There are no currently acceptable oncogenicity studies on maneb. The supplementary classification of the 31-month rat feeding study, may with additional data and clarifications as stated above, be upgraded. There were indications of thyroid oncogenicity in rats fed 0.25% Maneb for 1-2 years. A metabolite of maneb, ETU has been demonstrated to have oncogenic effects on the thyroid.

There are two published mouse oncogenicity studies on Maneb. Innes *et al*. (1969) reported negative results from F_1 C57BL/6 x C3H/Anf and C57BL/6 x AKR mice, which received the test material from 7 days of age (doses: 46.4 mg/kg/day through day 28; then 158 ppm (23.7 mg/kg/day) in the diet) to about 18 months. Balin (1970) reported a significantly increased incidence of lung adenomas in mice receiving 500 mg/kg/week of maneb. Neither of these studies is acceptable by the review criteria currently used by the Agency.

Rat and mouse oncogenicity studies are required.

Teratogenicity Testing - There are no acceptable teratogenicity studies for maneb. Because of anticipated human exposure to maneb, studies on two mammalian species (preferably rat and rabbit) are required to support all registered uses.

Reproduction Study - There is no accceptable reproduction study on maneb.

In an unpublished three-generation rat (Sprague-Dawley strain) study, the animals were fed dietary levels of 0, 30, 100 or 500 ppm (0, 1.5, 5, 25 mg/kg/day). In another unpublished three-generation rat (Chr-CD Strain) study, dietary levels of 0, 125 and 250 ppm (0, 6.25, 12.5 mg/kg/day) were given. There was no evidence of toxicity or reproductive and/or teratogenic effects in either study. Since no effects of any kind were reported, it appears that for both studies the test material was not administered at either a maximally tolerated dose or sufficiently close to it.

An acceptable two-generation reproduction study is required to support the continued registration of maneb for use on food crops.

Mutagenicity Studies - In response to the January 17, 1983, Data Call In Notice, several mutagenicity studies were submitted.

Gene Mutation - Five tester strains of *Salmonella typhimurium* were used to test 0, 3, 10, 15, 30, 50, and 100 ug/plate of technical maneb. The results were negative for base pair substitutions and frame-shift mutations, with and without metabolic activation. The ability of maneb to induce forward mutations at the HGPRT locus in Chinese Hamster Ovary (CHO) cells was evaluated in two different studies in the presence and absence of a metabolic activation system. In the first study, maneb did not exhibit mutagenic activity. In the second study, maneb was found not to induce an increase in mutation frequency with and without S-9 activation.

In a host-mediated assay in mice, maneb did not demonstrate a mutagenic response when tested using *Salmonella typhimurium* strain TA1530 as the indicator strain and B6C3F1 mice as the host.

Structural Chromosomal Aberration - Maneb was found to be negative for induction of Sister Chromatid Exchange in CHO cells in the absence of a metabolic activation system and positive with activation.

Other Mutagenic Mechanisms - Technical maneb was tested for induction of unscheduled DNA synthesis (UDS) using rat hepatocytes *in vitro*. Although maneb did not appear to induce unscheduled DNA synthesis under the conditions of the assay, sufficient evidence of the validity of the experiment was not provided in that individual data were not submitted. Once these are provided, the study may be upgraded to acceptable status.

The January 17, 1983, Data Call In Notice required a mammalian cell transformation assay on maneb (with and without metabolic activation) in a cell system capable of detecting initiation, as well as enhancement, of transformation. In one of the studies submitted, maneb, at five concentrations ranging from 0.05 to 0.20 ug/ml, did not induce transformation in C3H-10T 1/2 cells in the absence of metabolic activation. In another study, under the conditions of the cell transformation assay, maneb showed no indication of any promotion activity as a result of sequential exposure of C3H-10T 1/2 cells to MNNG and technical maneb.

Two of the mutagenicity studies require additional data in order to upgrade their status to acceptable. Clarification of the percent of active ingredient is required for the CHO/HGPRT forward mutation assay and individual data are required for a final evaluation of the unscheduled DNA synthesis assay in rat hepatocytes.

Metabolism Studies - In an adequate study, the metabolism of maneb was studied in three groups of rats. The data indicate that in all three groups more than 70% of the ^{14}C was excreted in the urine and feces, and 20 to 30% of the ^{14}C in urine was ETU in the first 12 hours after dosage. ETU was 40 to 50% of the ^{14}C present in fecal samples in the period from 12 to 24 hours after dosage from rats dosed at 2235 mg/kg, but it was only 3.7 to 12% of the ^{14}C in feces from rats which received 25 mg/kg doses of ^{14}C-labeled maneb. The thyroid was a target organ; 0.3% of the total dose was present per gram of this organ at day 5 in females receiving a single 25 mg/kg dose. Females at 2235 mg/kg, on day 7, had mean ug maneb equivalents per gram organ weight of 218, 235 and 363 for thyroid, kidneys and liver, respectively.

An additional single-dose metabolism study was submitted which supports the results from the previous study; (i.e. the liver, kidneys, and thyroid contained the highest levels of Maneb; the major metabolite was ETU; and total excretion was greater than 70%).

No additional metabolism data are required.

Dermal Absorption - In an unpublished study, mixtures of ^{14}C-labeled and unlabeled maneb were applied at dosage levels of 0.195, 1.92, 19 or 133 mg total maneb to approximately 4.9 cm^2 of rat skin for a period of 10 hours. The study demonstrates that the amount of maneb bound to the skin following dermal exposure is concentration and/or dose dependent. At the lowest dose level of 0.195 mg/rat approximately 30% of the radioactivity (approximately 0.06 mg maneb) was bound to the rat skin; at the highest dose level of 133 mg/rat approximately 0.7%, or 0.9 mg maneb, was bound to the skin.

The amount of ^{14}C activity excreted in the urine during the period from 4 to 10 hours following application of the test material is about 1% of the amount bound to the skin at each dose level. This represents the lower limit of absorption. Since ^{14}C activities were only measured for urine, blood and feces (not for carcasses), the study does not adequately define the upper limit for absorption.

While the study is acceptable as core minimum data, additional work is necessary to determine what levels of ^{14}C activity are associated with the carcass in order to obtain a more precise measurement of the amount of maneb absorbed. Additionally studies are also required to determine whether (and if so, at what rate) the maneb bound to the skin is absorbed after 10 hours.

Toxicological Studies - ETU - Since ETU, a contaminant, degradation product, and metabolite of maneb and other EBDC products, presents toxicological concerns, available data on ETU were considered in the overall evaluation of maneb. These data are summarized as follows:

Subchronic Studies - During a 90-day rat feeding study with mancozeb, an additional group of animals received 250 ppm (12.5 mg/kg/day) ETU. Compound related effects in this group were generally comparable to those observed at 1000 ppm (50 mg/kg/day) mancozeb (depressed body weight and changes in hormone levels accompanied by diffused hyperplasia of thyroid follicular epithelium). Residue analysis for ETU in mancozeb-treated animals revealed that no ETU was present in blood.

In a rat study conducted to examine the subchronic effects of ETU on the thyroid, levels of 50, 100, 500, and 750 ppm (2.5, 5, 25, 37.5 mg/kg/day) ETU were fed for 30, 60, 90, and 120 days. A NOEL was not determined in this study due to effects of ETU seen on thyroid weights at all dosage levels at 120 days. In a second study, rats were fed levels of 0, 1, 5, 25, 125, and 625 ppm (0, .05, .25, 1.25, 6.25 31.25 mg/kg/day) ETU for 30, 60, and 90 days. Thyroid hyperplasia, decreased uptake of ^{125}I by the thyroid, and decreased serum T_3 (triiodothyronine) and T_4 (tetraiodothyronine) were seen. The LEL was 25 ppm for these effects with 5 ppm (0.25 mg/kg) considered the NOEL.

In a 90-day mouse study, ETU fed at levels of 0, 1, 10, 100, and 1000 ppm (0, .15, 1.5, 15, 150 mg/kg/day) resulted in increased thyroid weights in females and an increased incidence of follicular cell hyperplasia in both sexes at levels of 100 ppm (15 mg/kg/day) and higher. Liver toxicity was only observed at the highest level, 1000 ppm (15 mg/kg/day).

In a 21-week study in Rhesus monkeys, at dosage levels of 0, 2, 10, 50, and 250 ppm (0, .10, 0.5, 2.5, 12.5 mg/kg/day), serum thyroid hormone concentrations were measured as well as iodine uptake in the thyroid. Mild to moderate pituitary hypertrophy was seen at 50 and 250 ppm (2.5, 12.5 mg/kg/day) as well as thyroid follicular lining cell hypertrophy and hyperplasia (mild at 50 ppm (2.5 mg/kg/day); moderate to severe at 250 ppm) (12.5 mg/kg/day). Serum levels of T_4 were significantly decreased in the 250 ppm (12.5 mg/kg/day) group. Free serum T_4 levels were also significantly decreased in both the 50 and 250 ppm (2.5, 12.5 mg/kg/day) group; iodine uptake was significantly increased at these levels and thyroid stimulating hormone (TSH) levels were significantly increased at 250 ppm (12.5 mg/kg/day).

In a 6-month Rhesus monkey study, at dosage levels of 0, 50, 150, and 450 ppm (0, 2.5, 7.5, 22.5 mg/kg/day), pituitary as well as thyroid hormone levels were measured. A NOEL was not demonstrated.

Oncogenicity Studies - Three oncogenicity studies have been reviewed, as discussed below:

In a mouse study (Innes), two hybrid strains of mice were used [(C57BL/6 x C3H/Anf)F_1 (Strain X) and (C57BL/6 x AKR)F_1 (Strain Y)]. Eighteen mice per sex per group were used in the treatment group. Only one dose was tested which was stated to be the maximum tolerated dose. When the mice were 7 days old, 215 mg/kg ETU was given by stomach daily. At 28 days of age, the mice were given diets containing 646 ppm (96.9 mg/kg/day) of ETU. The mice were sacrificed after a total of 83 weeks of treatment. Histopathology consisted of examination of all major organs and of all grossly visible lesions. Thyroid glands were not examined. The incidence of liver tumors, which were not classified as adenomas or carcinomas but only as hepatomas, is outlined in the following table:

	Male		Female	
	Control	Treated	Control	Treated
Strain X	3/14	14/16	0/18	18/18
Strain Y	1/18	18/18	0/18	9/16

Totals: Controls - 4/68 Treated - 59/68

In a study with Charles River CD-1 rats, 175 or 350 ppm (8.75, 17.5 mg/kg/day) ETU was administered in the diet for 18 months. At that time, 5 rats/sex were sacrificed and the remaining rats were placed on control diets until termination of the study at 24 months. The control group consisted of 32 male and 36 female rats. No thyroid lesions were seen in the control group. The incidence of thyroid lesions in the ETU-treated rats is presented below. The number of animals examined was not given.

	350 ppm		175 ppm	
Lesion	Males*	Females	Males*	Females
Thyroid carcinoma** (follicular)	17	8	3	3
Thyroid solid cell ademona	0	1	0	2
Hyperplastic goiter	17	13	9	6
Simple goiter	2	4	4	2

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*All five male rats in the high-dose group sacrificed at 18 months had hyperplastic goiter; 3 had follicular thyroid cancer.

**Two with lung metastases.

In a 2-year study, Charles River rats were placed on diets containing 0, 5, 25, 125, 250, or 500 ppm (0, .05, .25, 12.5 25 mg/kg/day) ETU. Body weight gain was adversely affected at the highest dose tested at 18 and 24 months for both males and females. ^{131}I uptake was statistically increased in male rats at 18 months in the 25 and 125 ppm (.25, 12.5 mg/kg/day) groups and decreased at 500 ppm (25 mg/kg/day). At 24 months in the male rats, ^{131}I uptake was significantly increased in the 5 ppm (0.05 mg/kg/day) group and decreased in the 500 ppm (25 mg/kg/day) group. Because of large variability in the values obtained, there were no statistically significant differences in ^{131}I uptake in female rats.

Histopathology incidence data were combined for males and females. An increase in the number of rats with cataracts/keratitis and with thyroid follicular adenocarcinoma/carcinoma was observed in the groups fed 250 and 500 ppm (12.5, 25 mg/kg/day) ETU; with thyroid adenomas in the 250 ppm (12.5 mg/kg/day) group; and with thyroid hyperplasia in the 5, 25, 125, and 250 ppm (.05, .25, 6.25 mg/kg/day) groups. The LEL is 5 ppm (0.25 mg/kg/day) for the effects of ETU on the thyroid in this study. Relevant data are summarized as follows:

Tumor Incidence Data for Rats,
Including 18-Month Interim
Sacrifice, Fed ETU in the Diet

	Dose Levels in ppm					
	0	5	25	125	250	500
Pathological lesions						
Cataracts/keratitis	2	1	0	2	6	12
Thyroid carcinoma/ adenocarcinoma (follicular)	2	2	1	2	16	62
Thyroid adenomas	2	--	5	1	21	3
Thyroid hyperplasia	4	20	41	44	27	3
Parathyroid hyperplasia	6	11	8	2	3	0
Number of Rats per Group	72	75	73	73	69	70

Statistics were not reported on the histopathological data. Historical control data were not available. More detailed information on this study is not available.

Teratology Studies - ETU has been shown to be a teratogen in studies with rats and hamsters. In rats, it produces a wide variety of anomalies in the central nervous, urogenital and skeletal systems as well as other organs at dosages that do not produce maternal toxicity or fetotoxicity. The NOEL for these effects is 5 mg/kg. Administration of T_3/T_4 with ETU to pregnant rats appears to reduce the incidence of some of these effects.

Mutagenicity Studies - Results of short-term assays indicate that ETU is weakly genotoxic; ETU has been shown to give mixed results for gene mutation in both bacterial and mammalian cell lines, but positive results for DNA repair in human cells, yeast, and bacteria. Although reportedly positive in one mammalian cell transformation assay using hamster cells, an adequate assay in mouse cells was negative.

Metabolism Studies - In a study with Rhesus monkeys, 50 percent of an administered dose of ^{14}C-ETU was excreted in the urine within 24 hours and 90 percent within 72 hours. Only 0 to 0.68 percent of the label was eliminated in the feces at 24 hours and no radioactivity was found at the 48- and 72-hour sampling periods.

In another study with Wistar rats, ^{14}C-ETU was predominantly excreted in the urine. The ratio of urine to fecal excretion varies with dose, i.e., for 0.1 ppm ETU the ratio was 55/25, and at 10 ppm ETU the ratio was 70/10. Minimal radioactivity was recovered as $^{14}CO_2$ ($\leq 0.5\%$). The level of radioactivity plateaued in the thyroid gland after 8 days of dosing and declined rapidly once dosing was terminated.

Structure Activity Information - ETU is structurally related to thiourea, methimazole, propylthiouracil, and thiouracil, all thyroid inhibitors. Chronic studies on thiourea in rats have shown that it induces hepatomas and thyroid enlargement. Methimazole, propylthiouracil and thiouracil all induce thyroid tumors in rats. Propylthiouracil also induces thyroid tumors in hamsters and guinea pigs and pituitary adenomas in mice. Thiouracil induces hepatomas and thyroid tumors in mice.

Risk Assessment - The Agency does not have any acceptable oncogenicity data on maneb. However, based on the data available on ETU, as discussed in the preceding section, the Agency has classified ETU, in accordance with the Agency's

Guidelines for Carcinogen Risk Assessment (September 26, 1986, 51 FR 33992), as a Group B2 oncogen, Probable Human Carcinogen.

These guidelines categorize the evidence on carcinogenicity of chemicals in terms of how likely it is that the chemical is a human carcinogen. Under this scheme, Group B2 categorization is appropriate if there is "sufficient evidence" of the chemical's carcinogenicity from animal studies. "Sufficient evidence" is defined as an increased incidence of malignant tumors (or combined malignant and benign tumors) in multiple species or strains, in multiple experiments, or to an unusual degree with regard to incidence, site or type of tumor, or age at onset.

ETU induced an increased incidence of thyroid adenomas and adenocarcinomas in two separate studies with rats and hepatomas in two strains of mice. Furthermore, ETU induced thyroid tumors in rats after 1 year or less of treatment and induced both thyroid tumors in rats and hepatomas in mice to a high degree in a single experiment.

The classification as a Group B2 oncogen is also supported by positive structure-activity data since several other thyroid inhibitors (i.e., thiouracil and thiourea) have been found to induce hepatomas and/or thyroid tumors in rodents.

EPA acknowledges that the studies considered in arriving at its classification of ETU were not carried out in accordance with EPA guidelines for oncogenicity studies. EPA, however, does consider the studies adequate to conclude that ETU is oncogenic to rats and mice due to the magnitude of the response seen. The Agency's conclusions regarding the classification of ETU will be reconsidered when results of additional studies on ETU are available.

Worker Exposure and Risks - The Agency is currently assessing risks associated with systemic effects of maneb and the teratogenic, thyroid and oncogenic effects attributed to ETU. Information available to the Agency about use practices indicates that aerial loading and application are generally performed by different people. For other application methods (ground boom, airblast, sprinkler and seed treatment), loading and application are generally performed by the same person. Mixer/loaders and applicators are also exposed to ETU in the tank mix. Available data indicate that the concentration of ETU as a contaminant can vary between products. For calculating direct exposure to mixers and loaders while preparing and loading maneb spray mixture, the Agency used 0.1% of the maneb exposure. This represents the typical level of ETU contamination of EBDC products for which we have data. The pesticide applicator is exposed not only to the amounts of ETU which contaminates the technical and tank mix but also the additional ETU formed while spraying. Available data indicate that ETU residues increase in the spraying equipment to 6% of the amount of maneb products.

An oral subchronic study of maneb in monkeys showed thyroid effects at 15 mg/kg, with a NOEL of 5 mg/kg/day. No developmental studies were available.

ETU has been shown to be a teratogen in studies with rats and hamsters. In rats, it produces a wide variety of anomalies in the central nervous, urogenital and skeletal systems. The NOEL for these effects is 5 mg/kg/day.

In assessing teratogenic margins of safety, the Agency has assumed 30 percent dermal absorption based on a dermal absorption study for the ETU contaminant in the tank mix and added a 20 percent conversion factor for metabolic conversion of maneb to ETU. A 30 percent dermal absorption figure was used for maneb in the absence of adequate data. The exposures to applicators and the margins of safety for teratogenic effects of ETU from exposure to maneb and ETU in the tank mix are shown in Table 2.

ETU has also demonstrated thyroid hyperplasia, decreased uptake of ^{125}I (iodine) by the thyroid and decrease serum T_3 and T_4 in a subchronic feeding study in rats. The NOEL for these effects is 5 ppm (0.25 mg/kg/day). Margins of safety for thyroid effects were calculated for direct exposure to ETU and are given in Table 3.

The Agency has also calculated the oncogenic risk to loaders and applicators from exposure to ETU both from maneb absorbed and metabolized to ETU and from direct exposure to ETU as a contaminant in the tank mix. The exposures and risks are given in Table 3. The range of oncogenic risk is 3×10^{-7} to 4×10^{-4}

TABLE 2

NONDIETARY RISK ASSESSMENT FOR MANEB

		mg/kg/day MANEB DERMAL EXPOSURE	mg/kg/day a/ MANEB ABSORBED DERMALLY	mg/kg/day MANEB INHALATION EXPOSURE	MANEB TOTAL DAILY EXPOSURE mg/kg/day	mg/kg/day b/ MANEB METABOLIZED TO ETU	mg/kg/day ETU DERMAL EXPOSURE	mg/kg/day c/ ETU ABSORBED DERMALLY	mg/kg/day ETU FROM INHALATION EXPOSURE	ETU TOTAL DAILY EXPOSURE mg/kg/day
APPLES:										
AERIAL	LOADER	0.2300	0.0690	0.0035	0.0725	0.0145	0.0002	0.0001	0.0000	0.0146
	APPLICATOR	0.0081	0.0024	0.0003	0.0027	0.0005	0.0005	0.0002	0.0000	0.0007
AIRBLAST	LOADER	0.9400	0.2820	0.0140	0.2960	0.0592	0.0009	0.0003	0.0000	0.0595
	APPLICATOR	2.2000	0.6600	0.0033	0.6633	0.1327	0.1300	0.0390	0.0002	0.1719
	COMBINE	3.1400	0.9420	0.0170	0.9590	0.1918	0.1309	0.0393	0.0002	0.2313
ONIONS:										
AERIAL	LOADER	0.5000	0.1500	0.0077	0.1577	0.0315	0.0005	0.0002	0.0000	0.0317
	APPLICATOR	0.0140	0.0042	0.0004	0.0046	0.0009	0.0008	0.0003	0.0000	0.0012
	FLAGGER	0.0780	0.0234	0.0044	0.0278	0.0056	0.0002	0.0000	0.0000	0.0056
GROUNDBOOM	LOADER	0.2100	0.0630	0.0032	0.0662	0.0132	0.0002	0.0001	0.0000	0.0133
	APPLICATOR	0.4700	0.1410	0.0086	0.1496	0.0299	0.0280	0.0084	0.0005	0.0388
	COMBINE	0.6800	0.2040	0.0118	0.2158	0.0432	0.0282	0.0085	0.0005	0.0521
POTATOES:										
AERIAL	LOADER	1.9000	0.5700	0.0290	0.5990	0.1198	0.0019	0.0006	0.0000	0.1204
	APPLICATOR	0.0380	0.0114	0.0012	0.0126	0.0025	0.0023	0.0007	0.0001	0.0033
	FLAGGER	0.0210	0.0063	0.0120	0.0183	0.0037	0.0130	0.0039	0.0007	0.0083
GROUNDBOOM	LOADER	0.2200	0.0660	0.0034	0.0694	0.0139	0.0002	0.0001	0.0000	0.0139
	APPLICATOR	0.2900	0.0870	0.0053	0.0923	0.0185	0.0170	0.0051	0.0003	0.0239
	COMBINE	0.5100	0.1530	0.0087	0.1617	0.0323	0.0172	0.0052	0.0003	0.0378
CHEMGATION	COMBINE	1.6000	0.4800	0.0250	0.5050	0.1010	0.0016	0.0005	0.0000	0.1015
SEED TREAT	FILL/CUT	0.0840	0.0252	0.0058	0.0310	0.0062	0.0001	0.0000	0.0000	0.0062
	PLANT	0.0300	0.0090	0.0030	0.0120	0.0024	0.0000	0.0000	0.0000	0.0024

a/ 30% ETU DERMAL ABSORPTION
b/ 30% DERMAL ABSORPTION OF MANEB
c/ 20% METABOLIC CONVERSION OF MANEB TO ETU

NONDIETARY RISK ASSESSMENT FOR MANEB

		mg/kg/day MANEB DERMAL EXPOSURE	mg/kg/day a/ MANEB ABSORBED DERMALLY	mg/kg/day MANEB INHALATION EXPOSURE	MANEB TOTAL DAILY EXPOSURE mg/kg/day	mg/kg/day b/ MANEB METABOLIZED TO ETU	mg/kg/day ETU DERMAL EXPOSURE	mg/kg/day c/ ETU ABSORBED DERMALLY	mg/kg/day ETU FROM DIRECT INHAL. EXP	ETU TOTAL DAILY EXPOSURE mg/kg/day
TOMATOES:										
AERIAL	LOADER	1.2000	0.3600	0.0019	0.3619	0.0724	0.0012	0.0004	0.0000	0.0728
	APPLICATOR	0.0300	0.0090	0.0010	0.0100	0.0020	0.0018	0.0005	0.0001	0.0026
	FLAGGER	0.1700	0.0510	0.0095	0.0605	0.0121	0.0100	0.0030	0.0006	0.0157
GROUNDBOOM	LOADER	0.2000	0.0600	0.0031	0.0631	0.0126	0.0002	0.0001	0.0000	0.0127
	APPLICATOR	0.4000	0.1200	0.0073	0.1273	0.0255	0.0240	0.0072	0.0004	0.0331
	COMBINE	0.6000	0.1800	0.0104	0.1904	0.0381	0.0242	0.0073	0.0004	0.0458
SWEET CORN:										
GROUNDBOOM	LOADER	0.2000	0.0600	0.0030	0.0630	0.0126	0.0002	0.0001	0.0000	0.0127
	APPLICATOR	0.3000	0.0900	0.0056	0.0956	0.0191	0.0180	0.0054	0.0003	0.0249
	COMBINE	0.5000	0.1500	0.0086	0.1586	0.0317	0.0180	0.0054	0.0003	0.0375
GRAPES:										
GROUNDBOOM	LOADER	0.2400	0.0720	0.0037	0.0757	0.0151	0.0002	0.0001	0.0000	0.0152
	APPLICATOR	0.5700	0.1710	0.0009	0.1719	0.0344	0.0340	0.0102	0.0001	0.0446
	COMBINE	0.8100	0.2430	0.0046	0.2476	0.0495	0.0342	0.0103	0.0001	0.0598
COMMERCIAL ORNAMENTALS:										
	LOADER	0.0190	0.0057	0.0003	0.0060	0.0012	0.0000	0.0000	0.0000	0.0012
	APPLICATOR	2.9000	0.8700	0.0023	0.8723	0.1745	0.1700	0.0510	0.0001	0.2256
	COMBINE	2.9200	0.8760	0.0026	0.8786	0.1757	0.1700	0.0510	0.0001	0.2269
HOMEOWNER										
VEGETABLE	COMBINE	0.0890	0.0267	0.0000	0.0267	0.0053	0.0053	0.0016	0.0000	0.0069
ORNAMENTAL	COMBINE	0.0620	0.0186	0.0000	0.0186	0.0037	0.0037	0.0011	0.0000	0.0048
TURF	COMBINE	4.9000	1.4700	0.0000	1.4700	0.2940	0.2900	0.0870	0.0000	0.3810
FRUIT TREE	COMBINE	0.7700	0.2310	0.0000	0.2310	0.0462	0.0460	0.0138	0.0000	0.0600

a/ 30% DERMAL ABSORPTION OF MANEB
b/ 20% METABOLIC CONVERSION OF MANEB TO ETU
c/ 30% ETU DERMAL ABSORPTION

TABLE 3

NONDIETARY RISK ASSESSMENT FOR MANEB

		MANEB TOTAL DAILY EXPOSURE mg/kg/day	ETU TOTAL DAILY EXPOSURE mg/kg/day	DAYS EXPOSED	ETU TOTAL YEARLY EXPOSURE mg/kg	MANEB TOTAL YEARLY EXPOSURE mg/kg	ETU TOTAL DIRECT YEARLY EXPOSURE mg/kg	THYROID SEASONAL SYSTEMIC MANEB MOS 5 mg/kg	MOS TERATO ETU 5 mg/kg	THYROID SEASONAL SYSTEMIC ETU MOS .25 mg/kg	a/ ONCO RISK ETU
APPLES:											
AERIAL	LOADER	0.0725	0.0146	1	0.0146	0.0725	0.0001	6207	343	326087	7.98E-07
	APPLICATOR	0.0027	0.0007	1	0.0007	0.0027	0.0002	164835	7184	150000	3.81E-08
AIRBLAST	LOADER	0.2960	0.0595	7	0.4164	2.0720	0.0020	217	84	11398	2.28E-05
	APPLICATOR	0.6633	0.1719	7	1.2030	4.6431	0.2744	97	29	82	6.59E-05
	COMBINE	0.9590	0.2313	7	1.6190	6.7130	0.2764	67	22	81	8.87E-05
ONIONS:											
AERIAL	LOADER	0.1577	0.0317	6	0.1901	0.9462	0.0009	476	158	25000	1.04E-05
	APPLICATOR	0.0046	0.0012	6	0.0072	0.0276	0.0017	16304	4174	13489	3.94E-07
	FLAGGER	0.0278	0.0056	6	0.0336	0.1668	0.0003	2698	892	78125	1.84E-06
GROUNDBOOM	LOADER	0.0662	0.0133	6	0.0798	0.3972	0.0004	1133	376	59524	4.37E-06
	APPLICATOR	0.1496	0.0388	6	0.2330	0.8976	0.0535	501	129	420	1.28E-05
	COMBINE	0.2158	0.0521	6	0.3128	1.2948	0.0539	348	96	418	1.71E-05
POTATOES:											
AERIAL	LOADER	0.5990	0.1204	4	0.4815	2.3960	0.0023	188	42	9868	2.64E-05
	APPLICATOR	0.0126	0.0033	4	0.0131	0.0504	0.0030	8929	1524	7401	7.19E-07
	FLAGGER	0.0183	0.0083	4	0.0331	0.0732	0.0185	6148	604	1218	1.81E-06
GROUNDBOOM	LOADER	0.0694	0.0139	7	0.0976	0.4858	0.0005	926	359	48701	5.35E-06
	APPLICATOR	0.0923	0.0239	7	0.1672	0.6461	0.0379	696	209	593	9.16E-06
	COMBINE	0.1617	0.0378	7	0.2647	1.1319	0.0384	398	132	587	1.45E-05
CHEMGATION	COMBINE	0.5050	0.1015	2	0.2030	1.0100	0.0010	446	49	23438	1.11E-05
SEED TREAT	FILL/CUT	0.0310	0.0062	5	0.0312	0.1550	0.0002	2903	803	150000	1.71E-06
	PLANT	0.0120	0.0024	5	0.0120	0.0600	NEGL.	7500	2083	>>>>100	6.58E-07

a/ RISK = YEARLY EXPOSURE/365 X 40/70 X 0.14/mg/kg/day

NONDIETARY RISK ASSESSMENT FOR MANEB

		MANEB TOTAL DAILY EXPOSURE mg/kg/day	ETU TOTAL DAILY EXPOSURE mg/kg/day	DAYS EXPOSED	ETU TOTAL YEARLY EXPOSURE mg/kg	MANEB TOTAL YEARLY EXPOSURE mg/kg	ETU TOTAL DIRECT YEARLY EXPOSURE mg/kg	THYROID SEASONAL SYSTEMIC MANEB MOS 5 mg/kg	MOS TERATO ETU 5 mg/kg	THYROID SEASONAL SYSTEMIC ETU MOS .25 mg/kg	a/ ONCO RISK ETU
TOMATOES:											
AERIAL	LOADER	0.3619	0.0728	3	0.2183	1.0857	0.0011	414	69	19789	1.20E-05
	APPLICATOR	0.0100	0.0026	3	0.0078	0.0300	0.0018	15000	1925	12563	4.27E-07
	FLAGGER	0.0605	0.0157	3	0.0470	0.1815	0.0107	2479	319	2101	2.58E-06
GROUNDBOOM	LOADER	0.0631	0.0127	7	0.0888	0.4417	0.0004	1019	394	53571	4.86E-06
	APPLICATOR	0.1273	0.0331	7	0.2317	0.8911	0.0535	505	151	421	1.27E-05
	COMBINE	0.1904	0.0458	7	0.3205	1.3328	0.0539	338	109	417	1.76E-05
SWEET CORN:											
GROUNDBOOM	LOADER	0.0630	0.0127	4	0.0506	0.2520	0.0002	1786	395	93750	2.77E-06
	APPLICATOR	0.0956	0.0249	4	0.0994	0.3824	0.0229	1177	201	981	5.45E-06
	COMBINE	0.1586	0.0375	4	0.1498	0.6344	0.0230	709	133	980	8.21E-06
GRAPES:											
GROUNDBOOM	LOADER	0.0757	0.0152	15	0.2282	1.1355	0.0011	396	329	20833	1.25E-05
	APPLICATOR	0.1719	0.0446	15	0.6694	2.5779	0.1538	175	112	146	3.67E-05
	COMBINE	0.2476	0.0598	15	0.8975	3.7140	0.1547	121	84	145	4.92E-05
COMMERCIAL ORNAMENTALS:											
	LOADER	0.0060	0.0012	30	0.0370	0.1797	0.0010	2504	4056	87656	2.03E-06
	APPLICATOR	0.8723	0.2256	30	6.7680	26.1690	1.5342	17	22	59	3.71E-04
	COMBINE	0.8786	0.2269	30	6.8058	26.3580	1.5342	17	22	59	3.73E-04
HOMEOWNER											
VEGETABLE	COMBINE	0.0267	0.0069	6	0.0416	0.1602	0.0095	2809	3145	2358	2.28E-06
ORNAMENTAL	COMBINE	0.0186	0.0048	5	0.0242	0.0930	0.0056	4839	4505	4054	1.32E-06
TURF	COMBINE	1.4700	0.3810	2	0.7620	2.9400	0.1740	153	57	129	4.18E-05
FRUIT TREE	COMBINE	0.2310	0.0600	6	0.3600	1.3860	0.0828	325	362	272	1.97E-05

a/ RISK = YEARLY EXPOSURE/365 X 40/70 X 0.14/mg/kg/day

NONDIETARY RISK ASSESSMENT FOR MANEB

GRAPES:		MANEB TOTAL DAILY EXPOSURE mg/kg/day	ETU TOTAL DAILY EXPOSURE mg/kg/day	THYROID DAILY SYSTEMIC MANEB MOS 5 mg/kg	THYROID SEASONAL SYSTEMIC MANEB MOS 5 mg/kg	MOS TERATO ETU 5 mg/kg	THYROID DAILY SYSTEMIC ETU MOS .25 mg/kg	THYROID SEASONAL SYSTEMIC ETU MOS .25 mg/kg	a/ ONCO RISK ETU
GROUNDBOOM	LOADER	0.0757	0.0152	66	396	329	16	20833	1.25E-05
	APPLICATOR	0.1719	0.0446	29	175	112	6	146	3.67E-05
	COMBINE	0.2476	0.0598	20	121	84	4	145	4.92E-05
COMMERCIAL ORNAMENTALS:									
	LOADER	0.0060	0.0012	835	2504	4056	203	87656	2.03E-06
	APPLICATOR	0.8723	0.2256	6	17	22	1	59	3.71E-04
	COMBINE	0.8786	0.2269	6	17	22	1	59	3.73E-04

a/ RISK = YEARLY EXPOSURE/365 X 40/70 X 0.14/mg/kg/day

Dietary Exposure and Risk. The Agency has assessed dietary risks attributed to exposure to ETU resulting from application of maneb to crops. Risk assessments were calculated for certain chronic adverse effects from chronic dietary exposure to ETU and maneb. In addition, oncogenicity and teratology dietary risk assessments were calculated for ETU.

Chronic Effects

First, dietary exposure to ETU from use of maneb and potential risks for adverse effects from this exposure were assessed. Average field trial residues of ETU, obtained from studies submitted in support of maneb tolerances, were used for this dietary exposure analysis. ETU residues for processed products were calculated by using the appropriate conversion factors, calculated from the available data, for each of the processed commodities since some maneb converts to ETU during the processing of the raw agricultural commodities. These residues were then reduced by the percent of crop treated with maneb obtained from actual use data, except a percent crop treated value of 10 was used for all commodities for which the estimated percent crop treated was less than 10. The results of this analysis indicate that the average consumer in the U.S. population receives a direct dietary exposure to ETU from maneb use of 0.0005 mg/kg/day.

The PADI for ETU was derived from the 2-year chronic feeding study in Charles River rats with an LEL of 0.25 mg/kg/day. An uncertainty factor of 3,000 was applied because a NOEL was not reached and the reproduction study is lacking and the follicular cell hyperplasia was observed in a significant number of animals at the LEL of 5 ppm. This resulted in a PADI of 0.00008 mg/kg/day. The effect on which the PADI is based was hyperplasia of the thyroid; a NOEL for this effect was not established for this study.

The dietary exposure to ETU of 0.0005 mg/kg/day occupies 580 percent of the PADI.

Secondly, dietary exposure to maneb and potential risks for adverse effects were assessed. The residues used in the analysis were the average field trial residues of maneb obtained from data submitted in support of established tolerances, reduced by the percent of crop treated. Based on these average residues, the average consumption estimate for the U.S. population is calculated as 0.0036 mg/kg/day maneb.

A PADI of 0.005 mg/kg/day for maneb was derived from a six month monkey study with a NOEL of 5.0 mg/kg/day and a safety factor of 1000 was used to account for the lack of an adequate data base on chronic toxicity. The effect noted was an increase in the mean thyroid weight.

The dietary exposure to maneb of 0.0036 mg/kg/day occupies 70 percent of the PADI.

Oncogenic Risks

Thirdly, a risk assessment was conducted to determine potential oncogenic risks from dietary exposure to ETU from use of maneb. For this assessment, average residues for both ETU and maneb from field trials were used. The Agency's Carcinogen Assessment Group derived risk models based on various bioassays on ETU. The most sensitive sex species end-point was found to be male mouse liver tumors in the Innes study. The potency, or Q_1^*, was calculated to be 0.14 $(mg/kg/day)^{-1}$.

Using the Tolerance Assessment System (TAS), the dietary exposure analysis indicates that the average consumer in the U.S. population receives a dietary exposure of 0.0005 mg/kg/day ETU from conversion of maneb on crops. This analysis was based on average field residues for ETU considering the percent of crop treated with maneb. The potential dietary risk is calculated by multiplying exposure by the Q_1^*:

$$\begin{aligned} \text{Dietary Risk} &= \text{Exposure} \times Q_1^* \\ &= 0.0005 \times 0.14 \\ &= 6.5 \times 10^{-5} \end{aligned}$$

In addition, there is dietary exposure from conversion of maneb to ETU in vivo after eating food containing maneb residues. Metabolism studies in rats show that approximately 20 percent of maneb is metabolically converted to ETU. In order to determine the dietary exposure to ETU from conversion of maneb residues in this way, the maneb dietary exposure of 0.0036 mg/kg/day is multiplied by 20 percent to yield an exposure of 7.3×10^{-4} mg/kg/day ETU. Multiplying this by the Q_1^* of 0.14 $mg/kg/day^{-1}$ yields a risk of 1.0×10^{-4} mg/kg/day.

The total potential dietary risk from exposure to ETU from use of maneb on food crops is obtained by adding $.65 \times 10^{-4}$ and 1.0×10^{-4}.

$$\text{Total Dietary Oncogenic Risk} = 1.7 \times 10^{-4}$$

Teratogenic Risks

Lastly, because ETU has been shown to be a teratogen in studies with rats and hamsters, an exposure and risk assessment was conducted for this effect. In rats, ETU produces a wide variety of anomalies in the central nervous, urogenital, and skeletal systems as well as other organs at dosages that do not produce maternal or fetotoxicity. The NOEL for these effects is 5 mg/kg/day.

Maneb and ETU crop residues were derived from studies submitted by the registrant. The analysis was conducted assuming that ETU was present uniformly in the food commodities at the maximum residues observed in field tests conducted closest to the maximum application rate, the minimum PHI, and the typical number of applications. The percent of crop treated is not appropriate because this is a single exposure.

The population subgroup of interest is females of child bearing age. The margin of safety (MOS) for acute exposure is calculated as the ratio of the NOEL to the estimated exposure. The estimate of the MOS for the average females is:

$$\begin{aligned} \text{MOS} &= (5 \text{ mg/kg}) / (0.0064 \text{ mg/kg}) \\ &= 770 \end{aligned}$$

Based on the TAS, ninety-eight percent of the females are estimated to have an MOS of at least 100, corresponding to an exposure of 0.05 mg/kg or less. The exposure distribution indicates that no member of the subgroup is expected to have an MOS of less than 70.

C. OTHER SCIENCE FINDINGS

Environmental Fate Available data are insufficient to fully assess the environmental fate of maneb. Available data indicate that maneb degrades to ETU and other transient degradates in water and soil. ETU is stable in water at pH 5 to 9 and under sunlight and the degradation of ETU in soil is not enhanced by sunlight radiation. ETU is the degradate of major environmental concern. Preliminary data from the Metiram and Mancozeb Registration Standards indicate that soil metabolism is the major route of degradation of ETU. Both maneb and ETU degrade in soil under aerobic conditions and slowly under anaerobic conditions. Acceptable anaerobic aquatic soil data on maneb and ETU indicate that maneb degrades very rapidly under anaerobic aquatic soil conditions but ETU is relatively stable under these conditions, having a degradation half life of 146 days.

Hydrolysis - Three studies were reviewed and considered to be unacceptable for maneb. There is acceptable ETU hydrolysis data which indicated that no detectable degradation of ETU occurred at pH 5, 7, and 9 in 30 days. Therefore, no breakdown of ETU due to hydrolysis is expected in the environment.

Photodegradation in Water - One study was reviewed and considered unacceptable for maneb. An acceptable ETU study indicated that no significant degradation of ETU occurred in a pH 7 water solution during the 30 day study period and thus no breakdown of ETU due to photodegradation is expected in the environment in absence of photosensitizers.

Photodegradation on Soil - One study was reviewed for maneb and considered unacceptable. An adequate ETU study exists that concluded that ethyleneurea (EU), carbamid and hydantoin degradation is facilitated by sunlight. On the other hand, ETU is formed at somewhat larger amounts on exposed soil but does not undergo photodegradation and dissipates only via aerobic soil degradation.

Anaerobic Aquatic Metabolism - Maneb degraded completely within an hour under anaerobic aquatic conditions to three major degradates: EBIS (ethylenebis(isothiocyanate)sulfide), ETU, EU and one major unidentified degradate. Levels of EU remained fairly constant from day 0 to day 275 at below 19.2%. EBIS degraded rapidly to ETU from 35% at day 0 to 4% after 3 days. ETU degraded very slowly from a maximum concentration of 38.6% on day 3 with an estimated half-life of 149 days. Thus, ETU is considered to be reasonably stable under aquatic anaerobic conditions and is of environnmental concern. The mean material balance (the amount of applied material recovered) was above 95% throughout the study period.

Ground water. Leaching and field dissipation data are insufficient to allow a final ground water assessment to be made, but available data indicate that maneb and ETU have moderate mobility in soils. Unidentified maneb residues were found in all soil leachate.

Degradation of ETU in soil under anaerobic aquatic conditions was reported and supplemental data also show moderate mobility of ETU and maneb in soils. It has been reported that ETU has been detected in ground water in Collier County, Florida.

Because ETU is a suspected leacher and an oncogen, the Agency also requires for its ground water assessment a small-scale retrospective ground water monitoring study to analyze specifically for maneb and ETU.

Ecological Effects. Available data are insufficient to completely evaluate the ecological effects of maneb. Data, as set forth in Table A, are either required or reserved pending further evaluation. The following conclusions can be made based on available data:

1. Toxicity to Birds. Based on subacute dietary studies, maneb can be characterized as practically nontoxic to birds ($LC_{50} >$ 9000 ppm).

2. Toxicity to Fish, Aquatic Invertebrates, and Estuarine/Marine Organisms. There is sufficient information to characterize the toxicity of an 80% product to warmwater fish as highly toxic. No studies were submitted for the acute aquatic invertebrate, fish and estuarine/marine organisms on the technical.

3. Risks to Nontarget Organisms (Including Endangered Species). The Agency has assessed the risks, based on the available data, from the aquatic, terrestrial and seed treatment uses of maneb. Based on these assessments, there does not appear to be a concern for acute effects to birds for any use of maneb. Additional data are required to complete a chronic risk assessment for these organisms as well effects on aquatic organisms.

    a. Terrestrial Organisms. Maneb's highest registered use rate is for turf (17.0 lbs. ai/A). A single application of maneb at 17.0 lb ai/A would result in an initial maximum residue level on short grass of 4080 ppm. This level is below the no effect level for both waterfowl and upland game species; therefore, there is no concern for acute exposure to endangered or non-endangered species. Since maneb can be applied at 3-5 day intervals, there is a potential for chronic exposure. An avian reproduction study is required to complete the hazard assessment to birds.

Regarding risk to avian species from the cranberry use, the 6.0 lb ai/A rate may, immediately after application, result in maximum estimated residues as follows: short grass-1440 ppm; forage and small insects-340 ppm; and berries-42 ppm. These residues are below the no effect level for the mallard duck and bobwhite quail. Therefore, neither endangered or non-endangered birds would be at risk from an acute exposure to maneb.

There are no avian acute oral studies on technical or single active products containing maneb. A hazard assessment of birds consuming treated seeds is not possible at this time. However, given the practically non-toxic nature of maneb there would not appear to be a concern for endangered or non-endangered birds.

b. Aquatic Organisms. Maneb is registered for use on cranberries at 3.0 to 6.0 lbs ai/A by both ground and air equipment. Cranberry bogs are likely to contain drainage canals and/or small streams leading into open water, such as ponds or embayments. Careless aerial application could result in direct contamination of a 6 foot deep water body at 0.183 to 0.336 ppm. However, a more likely scenario would be a 300 meter stream drainage canal receiving input via direct application and runoff from the surrounding 10 acres. In turn, the stream/drainage canal empties into the 1 acre, 6 foot pond. In addition, the pond may receive 5% of a single acre application rate via drift. The resulting maneb concentrations would be .074 to .148 ppm for 3.0 to 6.0 lbs, respectively.

Aquatic toxicity data on an 80% WP for rainbow trout (0.20 ppm) and bluegill sunfish (0.27 ppm) were recently received by the Agency (Aug. 1988). Based on a preliminary screen of these data and the previously mentioned exposure estimates for cranberries, rates of 5.0 lb ai and above may present a significant risk to fish. In these instances, the estimated environmental concentration (EEC) of 0.10 ppm and above exceeds one half the rainbow trout LC_{50} (0.20 ppm /2 = 0.10 ppm). Furthermore, even the lower rate of 3.0 lbs. ai would potentially exceed restricted use criteria. Although the endangered species trigger to fish (1/20 LC_{50} = 0.01 ppm) is also exceeded, there are no endangered fish associated with cranberry bogs.

Fish and aquatic invertebrates may be exposed to maneb used on golf courses when rainfall occurs soon after treatment. Assuming maneb to be sufficiently soluble for 5% runoff to occur, the residues in a 1 acre, 6 foot deep pond would be .119 ppm. This level exceeded the following criteria: 1) endangered fish (1/20 LC_{50} = 0.01 ppm), 2) restricted use (1/10 LC_{50} = 0.02 ppm). In keeping with the January 17, 1986, Biological Opinion on Diazinon, this could effect the Mohave Tui Chub on the China Lake Naval Weapons golf course. Therefore, the Agency will be consulting with the U.S. Fish and Wildlife Service.

Preliminary acute risk assessments have been conducted also for the major use patterns such as apples (6.8 lbs. ai/A), potatoes (1.6 lbs. ai/A) and sweet corn (2.25 lbs ai/A). Using models for runoff and assuming a 5 percent drift, residue levels in 6-foot ponds for the following crops would be corn (70 ppb), potato (48.8 ppb) and apples (145.18 ppb). Based upon these exposure estimates and the rainbow trout LC_{50} for the 80% WP (0.20 ppm), these uses exceed the restricted use criteria of 1/10 the LC_{50} to fish. However, these estimates are based on studies that have not been fully reviewed by the Agency. A final determination regarding restricted use will be made once the recently submitted fish toxicity studies are fully reviewed.

Reentry Consideration. Toxicity and exposure criteria are set forth in 40 CFR 158. If a chemical meets the specified criteria, reentry data are required.

Maneb does not meet the acute toxicity criteria, and there is no epidemiological evidence that residues of this pesticide cause adverse effects on persons entering treated sites. However, ETU has demonstrated evidence of oncogenicity, mutagenicity, teratogenicity and thyroid effects. Therefore, the chronic toxicity criteria have been met. Maneb meets the exposure criteria in that it is registered for use on crops which may involve substantial exposure to residues of the pesticides. Reentry data are required. Until the required data are submitted and evaluated and any change in this reentry interval is announced, in order to remain in compliance with FIFRA, an interim 24-hour reentry interval requirement for agricultural uses of maneb must be placed on the labels of all maneb end-use products.

D. TOLERANCE REASSESSMENT

Tolerances, expressed as zinc ethylene bisdithiocarbamate, have been established for residues of maneb in a variety of raw agricultural commodities (40 CFR 180.110). EPA has evaluated the residue and toxicology data supporting tolerances. The following were considered during this evaluation:

- Whether the current tolerances are sufficient to cover the actual residues resulting from use (including FIFRA section 24(c) and intrastate uses).
- Whether group tolerances can be established in accordance with 40 CFR 180.34(f).
- Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.
- Whether the tolerances are expressed accurately and in current terminology.

The regulatory results of the Agency's review are set out in Section IV.A, Regulatory Positions and Rationales.

Residue Data. The residue data reviewed in support of these tolerances include the following:

1. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of maneb. The metabolism is not completely understood. Metabolites identified thus far include ethylenethiourea (ETU), ethylenediamine (EDA), ethyleneurea (EU), hydantoin (HT), ethylenethiuram monosulfide (DIDT, EBIS) and 3-(2-imidazolin-2-yl)-2-imidazolidinethione (JB, Jaffe's base).

2. Analytical methodology for determining the levels of residues of maneb in plants and animals. Present colorimetric CS_2 evolution methods are adequate for collection of data pertaining to residues of maneb in or on plant and animal commodities. However, none of the colorimetric methods are specific for maneb and are therefore, inadequate for enforcement purposes.

3. Storage stability data. There is not sufficient information concerning the stability of maneb. Some storage stability data was submitted in response to the March 31, 1987 Notice. Storage stability data are being required.

4. Data on the magnitude of residues of maneb in individual raw agricultural commodities, animal products and processed food and feed items. Data are inadequate to support

tolerances. Data show that ETU concentrates on processing.

Toxicology Data. The toxicology data for maneb are insufficient to determine an Acceptable Daily Intake (ADI) or whether the toxicity observed in the studies is due to maneb or ETU.

There are no acceptable chronic studies on which to calculate an ADI, therefore, a subchronic study has been used to calculate a Provisional ADI (PADI). Because a subchronic study was used, an uncertainty factor of 1000 (rather than 100 used in chronic studies) was employed. The PADI for maneb is 0.005 mg/kg/day based on the six month monkey feeding study with a NOEL of 5 mg/kg/day.

The theoretical maximum residue contribution (TMRC), based on the assumption that 100 percent of each crop is treated and contains residues at the tolerance level, is 0.030 mg/kg/day or approximately 600 percent of the PADI. Based on a more realistic dietary assessment, using anticipated field residues and estimate of percent crop treated, the estimated average consumption for the U.S. population is 0.0036 mg/kg/day or 70 percent of the PADI.

Tolerances Issued. Currently, tolerances for maneb are expressed as zinc ethylene bisdithiocarbamate equivalents, as are the tolerances for other pesticides of the dithiocarbamate class. These tolerances are set forth in 40 CFR 180.110. There are several Canadian tolerances established for residues of EBDC's, including maneb, as well as several Codex Alimentarius tolerances. Several Mexican tolerances are established for residues of maneb.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on the review and evaluation of all available data on maneb, the Agency has made the following determinations. Where it is the Agency position that label revisions are needed in order for a product to remain in compliance with FIFRA, specific language will be set forth in Section D of this Chapter.

1. EPA is currently evaluating the potential human health risks resulting from the food, and field crop, and terrestrial non-food uses of maneb and the other EBDC pesticides containing the common contaminant, degradation product, and metabolite, ETU, in the EBDC Special Review.

   Rationale: The EBDC's were placed in Special Review in 1977 based on the presumption that the EBDC's and ETU posed potential risks to human health or the environment. The Special Review was concluded in 1982 and the EBDC's were returned to the registration process.

   In June 1987, the Agency initiated a Special Review of the EBDC pesticides because of concern about the oncogenic risk from dietary exposure to ETU from foods treated with these pesticides, and the risks of teratogenicity and adverse thyroid effects to applicators and mixer/loaders from exposure to ETU. ETU is present as part of the residue of the EBDC pesticides or their conversion on or in treated agricultural commodities. In addition, a portion of the EBDC pesticide residues converts to ETU in the body after ingestion of commodities with EBDC residues. The Special Review issues are discussed in the Background section of this document.

   ETU, a contaminant, degradation product, and metabolite of all the EBDC's, is mutagenic, oncogenic and teratogenic, and the Agency has classified it as a Group B2 oncogen (Probable Human Carcinogen). See the Agency Assessment section of this Standard for a discussion of the classification of ETU.

2. At this time, the Agency is not specifing restricted use classification for maneb-formulated products.

   Rationale. Based on recently submitted fish studies, a preliminary screen indicated that restricted use criteria may be met. The Agency is currently reviewing the data and will make a final determination concerning the need for restricted use classification for maneb as well as the other EBDC's.

3. The Agency will not consider establishment of any new food use tolerances for maneb at this time.

   Rationale: The current residue chemistry and toxicology data are not sufficient to assess existing and pending tolerances. The toxicology data base is insufficient to determine an ADI and also does not allow a decision as to whether observed toxicity is due to maneb or ETU. No new food uses will be considered until these issues are resolved.

4. The Agency will consider the need for establishment of tolerances for ETU and any intermediate metabolites when data are sufficient to permit such decisions.

   Rationale: The toxicology data base for maneb is insufficient to determine whether observed toxicity is due to maneb, ETU, or additional metabolites.

5. The Agency will not establish any food/feed additive regulations pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) and is deferring action on previously established food/feed additive regulations.

   Rationale: The Delaney Clause in Section 409 of the FFDCA bars the establishment of food additive regulations for substances which induce cancer in man or test animals, with certain exceptions. The Agency is currently developing a position relative to the Delaney Clause and FIFRA. Once this policy has been established, the Agency will determine what action is required in relation to pesticides which have produced positive oncogenic responses in chronic animal studies.

6. Maneb is currently registered for use on almond hulls, asparagus (post harvest treatment only), corn forage and sugar beet roots. The Agency is requiring the establishment of tolerances and submission of supporting data for the above uses.

   Rationale: Tolerances have not been established for almond hulls, asparagus, corn forage and sugar beet roots in which residues of maneb could occur. The registrant(s) must propose a tolerance and provide supporting data.

7. The Agency has determined that all data will be immediately reviewed as they are submitted.

   Rationale: Because of the concerns over ETU and the EBDC's, the Agency believes it is essential that all data be reviewed as they are received.

8. It is the Agency's position that, in order to remain in compliance with FIFRA, the importance of observing the preharvest intervals must be highlighted on labels of residential (homeowner) products. Language is specified herein.

   Rationale. In the 1982 Decision Document, the Agency determined that, as a risk reduction measure to reduce human dietary exposure, preharvest intervals must be highlighted on residential labels so that home garden users will be encouraged to comply with them. Although the risks from dietary exposure to maneb cannot be fully assessed at this time, the Agency believes continuation of this emphasis as a risk reduction measure is warranted. Specific language has been developed to emphasize to users the importance of adherence to the preharvest intervals.

9. The Agency is requiring reentry data for maneb. In order to remain in compliance with FIFRA, an interim 24-hour reentry interval requirement must be placed on the labels of all maneb end-use products registered for agricultural use, until the required data are submitted and evaluated and any change in this reentry interval is announced.

   Rationale. Maneb meets both the chronic toxicity and exposure criteria specified in 40 CFR 158.140 for reentry data. Until these data are received and evaluated, an interim 24-hour reentry interval will serve to reduce exposure of field workers to this chemical.

10. The Agency will evaluate the potential of maneb to contaminate ground water after it has received and evaluated additional required environmental fate data.

    Rationale. Maneb was identified as a chemical with the potential to contaminate ground water and a Data Call-In was issued. Results of the studies received were inconclusive. However, they demonstrate that ETU has the potential to leach. Additional data are required to fully assess the potential of maneb and ETU from the use of maneb to contaminate ground water. A small-scale retrospective monitoring study is also being required for maneb and ETU.

11. Maneb is currently registered for treatment of seed and planting stock for barley, corn (other than sweet corn), cotton, flax, oats, peanuts, pineapple, rice, rye, sorghum,

soybeans, sunflower and wheat. The Agency is requiring tolerances and supporting data for these treatments. Tolerances will be required at the maximum residue level, or, if residues are nondetectable, at the limit of detection.

Rationale: In the past, seed and planting stock treatments were considered to be nonfood uses. The Agency now requires tolerances to ensure that unacceptable residues do not occur in the commodities grown from treated seed or stock. For those crops for which seed or planting stock treatment is the only registered use and which have no tolerances for maneb, tolerances must be established to either reflect the maximum expected residue, or if no measurable residues are detected, the limit of detection of the analytical method.

12. In order to remain in compliance with FIFRA, it is the Agency's position that maneb products should continue to contain precautionary labeling pertaining to fish.

    Rationale: In the Decision Document to the Special Review concluded in 1982, the Agency concluded that the acute toxicity to aquatic organisms was not unreasonable as long as an appropriate warning was added to the label. No data have been submitted which modify the Agency's 1982 Position. In recently received acute studies that have not been fully reviewed, acute fish toxicity data indicate that the LC_{50} for both rainbow trout and bluegill was determined to be below 1 ppm for the 80 WP formulation of maneb, a level for which precautionary labeling is appropriate.

13. The Agency is not specifying endangered species labeling at this time.

    Rationale: Based on Jeopardy Opinion on Diazinon, the Mohave Tui Chub could be at risk from an acute exposure to maneb resulting from some of its registered uses. The Agency is consulting with the U.S. Fish and Wildlife Service. Endangered species labeling may be necessary in the future based on the results of this consultation.

14. The Agency is requiring analysis of maneb to determine whether nitrosamines may be formed.

    Rationale: There is a possibility for the formation of nitrosamines during the manufacture of maneb; however, the Agency does not have adequate data to determine whether nitrosamines actually are formed.

15. Protective clothing labeling for maneb products, as stipulated as a result of the 1982 Decision Document, should be updated as noted herein in order to remain in compliance with FIFRA.

Rationale: A major toxicological concern from exposure to maneb at this time is the hazard to the human thyroid from the degradation product, ETU, an acknowledged goitrogen, teratogen, and oncogen. Additional data are required to determine whether maneb also poses a teratogenic risk. The Agency believes that risks of teratogenicity and thyroid toxicity to commercial applicators can be reduced by maintaining the requirement that protective clothing be worn while mixing, loading and applying the chemical. The Agency believes that the same is true for other agricultural mixers, loaders, and applicators.

16. While data gaps are being filled, currently registered manufacturing-use products (MP's) and end-use products (EP's) containing maneb as the sole active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. However, significant new uses will not be registered. Registrants must provide or agree to develop and provide additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary. The Agency will not consider registration of any new uses while data gaps are being filled and data evaluated, based on its concerns for maneb and ETU as explained herein.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain maneb as the sole active ingredient, bear specified labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

Product Composition Standard - To be registered or reregistered under this Standard, manufacturing-use products (MP's) must contain maneb as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1% and any N-nitroso compounds at greater than 1 ppm.

Acute Toxicity Limits - The Agency will consider registration of technical grade and manufacturing-use products containing maneb provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

Use Patterns - To be registered under this Standrd, manufacturing-use products must be labeled for formulation into other manufacturing-use products or into end-use products bearing federally registered uses. The Use Index (EPA Compendium of Acceptable Uses) (for availability see page 7) lists all federally-registered uses of maneb, as well as approved maximum rates and frequencies.

D. LABELING

All maneb products must bear appropriate labeling as specified in 40 CFR 156.10. Appendix II contains information on label specifications.

In order to remain in compliance with FIFRA, no pesticide product containing maneb may be released for shipment by the registrant after November 1, 1989 unless the product bears an amended label which complies with the specifications of this Standard.

In order to remain in compliance with FIFRA, no pesticide product containing maneb may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after November 1, 1990 unless the product bears an amended label which complies with the specifications of this Standard.

In addition to the above, in order to remain in compliance with FIFRA, the following information must appear on the labeling:

1. Ingredient Statement. The ingredient statement for MP's and EP's must list the active ingredient as:

   Maneb (manganese ethylenebisdithiocarbamate)...... (%)
   (equivalent to manganese metallic ___%)

   Inert Ingredients................................. (%)

2. Use Pattern Statements. All manufacturing-use products must state that they are intended for formulation into end-use products only for acceptable use patterns.

However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

3. Disposal Statements. Because maneb has not been designated as an acute or toxic hazardous waste under the Resource Conservation and Recovery Act (RCRA), the following is the appropriate pesticide disposal statement for maneb products:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

The labels of all products must bear the appropriate container disposal statement (See Appendix III).

3. Precautionary Statements

Manufacturing-Use Products

"This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

End-Use Products

Outdoor Use (other than cranberries and seed treatment):

"This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment wash waters."

Seed Treatment Products:

"This pesticide is toxic to fish. Cover or incorporate spilled treated seed. Do not contaminate water when disposing of equipment wash waters."

Cranberry Use Products:

"This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters."

All Home Use Products:

> "PROTECTIVE MEASURES: Always spray with your back to the wind. Wear long-sleeve shirt, long pants, and rubber gloves. Wash gloves thoroughly with soap and water before removing. Change your clothes immediately after using this product and launder separately from other laundry items before reuse. Shower immediately after use."

Home Use Products with Food Uses:

> "Preharvest intervals on this label are specified so that pesticide residues will be at an acceptable level when the crop is harvested."

All Agricultural Products

> "After (sprays have dried/dusts have settled/vapors have dispersed, as applicable), do not enter or allow entry into treated areas or areas where there is a danger of drift until the 24-hour reentry interval has expired unless wearing the personal protective equipment listed on the label."
>
> "Keep all unprotected persons, children, livestock, and pets away from treated area or where there is danger of drift."
>
> "Do not rub eyes or mouth with hands. See First Aid (Practical Treatment Section)."

PERSONAL PROTECTIVE EQUIPMENT

> "HANDLERS (MIXERS, LOADERS, AND APPLICATORS) AND EARLY REENTRY WORKERS MUST WEAR THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT: a long-sleeve shirt and long pants or a coverall; chemical resistant gloves; shoes, socks, and goggles or a face shield. During mixing and loading, a chemical resistant apron must also be worn."
>
> "During application from a tractor with a completely enclosed cab with positive pressure filtration, or aerially with an enclosed cockpit, a long-sleeve shirt and long pants may be worn in place of the above protective clothing. Chemical resistant gloves must be available in the cab or cockpit and worn while exiting."
>
> "IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before eating, smoking or drinking.

Always wash hands and arms with soap and water before using the toilet."

"After work take off all clothes and shoes. Shower using soap and water. Wear only clean clothes. Do not use contaminated clothing. Wash protective clothing and protective equipment with soap and water after each use. Personal clothing worn during use must be laundered separately from household articles. Clothing and protective equipment drenched with maneb must be destroyed according to state and local regulations."

"DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED."

"During aerial application, human flaggers are prohibited unless in totally enclosed vehicles."

Grazing Statements As appropriate, the following grazing statements should appear on EP labels containing maneb:

For Almonds:

"If applied after petal fall, do not feed hulls to dairy animals or animals being finished for slaughter"

For Apples:

"Do not graze livestock in treated areas"

For Beans:

"Do not feed treated forage or hay to livestock"

For Corn (field, pop, sweet):

"Do not feed treated forage to livestock"

For Peanuts:

"Do not feed treated peanut hay to livestock"

For Potato (seed pieces), Agricultural Seed Treatment:

"Do not use treated seed pieces for food, feed or oil purposes"

For Sugar Beets:

"Do not feed treated tops to livestock"

For Ornamental Grasses (seed crop):

"Do not feed treated grass to livestock"

For Ornamental Turf:

"Do not graze treated areas. Do not feed clippings to livestock."

As appropriate, the following precautionary statements should appear on EP labels containing maneb:

For Celery, Collards, Kale, Mustard Greens, Turnips:

"Remove residues by stripping, trimming, and/or washing"

For Endive, Lettuce:

"Remove resiudes from head lettuce by striping and trimming and from leaf lettuce and endive by washing or other effective means"

For Peach:

"If applied within 14 days of harvest, remove residue by brushing"

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B[2]
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by an end use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to the data requirements in Table A.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will

submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Maneb Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately

notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

APPENDIX I

GUIDE TO TABLES

Tables A and B contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
Part 158 Subpart C - Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	Partially	00161800	Yes[3]	10/87[12]
61-3 - Discussion of Formation of Impurities	TGAI	All	Partially	00161800 00151415	Yes[4]	10/87[12]
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	Partially	00161800 00151415	Yes[5]	4/88[12][13]
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	Partially	00151415	Yes[6]	10/87[12]
63-3 - Physical State	TGAI	All	Partially	00151415	Yes[6]	10/87[12]
63-4 - Odor	TGAI	All	Partially	00151415	Yes[6]	10/87[12]
63-5 - Melting Point	TGAI		N/A	N/A	No[7]	
63-6 - Boiling Point	TGAI		N/A	N/A	No[8]	

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Fram for[2] Submissio
Part 158						
Subpart C - Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	N/A	Yes 4/	10/87 12/
63-8 - Solubility	TGAI or PAI	All	No	Yoder letter, 1985	Yes 6/ 9/	10/87 12/
63-9 - Vapor Pressure	TGAI or PAI	All	No	N/A	Yes 6/ 9/	10/87 12/
63-10 - Dissociation constant	TGAI or PAI	All	No	N/A	Yes 6/ 9/	10/87 12/
63-11 - Octanol/water partition coefficient	PAI	All	No	N/A	Yes 6 9/ 10/	10/87 12/
63-12 - pH	TGAI	All	No	N/A	Yes 6/ 11/	10/87 12/
63-13 - Stability	TGAI	All	No	N/A	Yes 6/	10/87 12/
Other Requirements:						
64- 1 - Submittal of samples	N/A	N/A	N/A	N/A	No	

1/ TGAI = Technical grade of the active ingredient, registered or unregistered. PAI = Purified active ingredient

2/ This data has previously been requested in the Comprehensive Data Call In Notice issued April 1987. The time frame for submission of data is the same as required in the April 1987 Data Call In Notice.

3/ For each technical product complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

4/ A detailed discussion must be submitted for each technical product of all impurities that are or may be present at $\geq$ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production.

5/ For all technical products, five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. The active ingredient in these samples must be analyzed for maneb per se using a method capable of differentiating maneb from interfering CS_2-liberating impurities. If the CS_2-liberation and maneb-specific methods yield different results, the CS_2-liberating impurities must be quantified. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

6/ As required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, data on color, physical state, and odor must be submitted for the 90% T Drexel and Aceto (EPA Reg. Nos 19713-64 and 2749-18), and the 86% T Drexel (EPA Reg. No. 19713-185). Specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability must be submitted for each technical.

7/ Data needed if the technical chemical is a solid at room temperature.

8/ Data needed if the technical product is a liquid at room temperature.

9/ Data submitted by the Maneb Task Force concerning an 88% T has been identified as a Rohm and Haas manufacturing-use product. EPA Reg. No. 707-103. The only requirements in common for any active ingredient, and that may be shared, are the analytical method for the active ingredient, solubility of the pure active ingredient (PAI), vapor pressure for the PAI, dissociation constant for the PAI, octanol/water partition coefficient for the PAI and the submittal of samples of the PAI. Therefore, product chemistry data submitted by the Maneb Task Force may not be shared unless it can be shown that the chemical composition of this T is the same as the other technical products for which data is wished to be shared.

10/ Data required if the technical product is organic and nonpolar.

11/ Data required if the test substance is dispersible in water.

12/ Data has been submitted by the Maneb Task Force and is currently being reviewed.

13/ All nitrosamines must be identified and quantified in six samples; two samples of each must be analyzed shortly after production, 3 months after production and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used.

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Fram for[2] Submissic
§158.240 - Residue Chemistry						
171-2 - Chemical Identity[3]						
171-3 - Directions for Use	--					6 Months
171-4 - Nature of Residue (Metabolism)						
- Plants	PAIRA		Partially	00088826 00088894 00088923 00088931 00159847 00159848 00159849 00159850	Yes[4][5]	10/88
- Livestock	PAIRA & Plant Metabolites		Partially	00159851 00159852	Yes[6][7]	10/88
171-4 - Residue Analytical Method	TGAI & Metabolites		Partially	00002931 00040149 00041799 00041800 00090132 00090152 00090174 00097198 00098644	Yes[8]	7/88[115]
171-4 - Storage Stability	TEP & metabolites		No		Yes[9][10][11]	9/88[115]
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use						
- Crop Group #1 - Root & Tuber Vegetables						
o Crop 1 Carrots						
-- Crop field trials	TEP		No		Yes[12][13][14]	10/88

TABLE A

GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Fra for[2] Submissi
§158.240 - Residue Chemistry - Continued						
171-4 - Magnitude of the Residue - Residue Studies						
o Crop 2 - Potatoes						
-- Crop Field Trials	TEP		No		Yes 15/16/	10/88
-- Processed Food/Feed	EP		No		Yes 17/	4/89
- Crop Group 3 - Sugar Beet Roots						
-- Crop Field Trials	TEP		No		Yes 18/20/21/	10/88
-- Processed Food/Feed	EP		No		Yes 19/	4/89
- Crop Group 4 - Turnip Roots						
-- Crop Field Trials	TEP		No		No 22/	
- Crop Group #2 - Leaves of Root & Tuber Vegetables						
o Crop 1 Sugar Beet Top						
-- Crop field trials	TEP		No		Yes 23/24/25/26/	10/88
o Crop 2 Turnip Tops						
-- Crop field trials	TEP		No		No 27/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
§158.240 - Residue Chemistry - Continued						
- Crop Group #3 - Bulb Vegetables						
o Crop 1 Onions						
-- Crop field trials	TEP		No		Yes[28][29][30][31]	10/88
- Crop Group #4 -Leafy Vegetables						
o Crop 1 Celery						
-- Crop field trials	TEP		No		Yes[32][33][34][35][36][37]	10/88
o Crop 2 Endive						
-- Crop field trials	TEP		No		No[38]	
o Crop 3 Lettuce						
-- Crop field trials	TEP		No		Yes[39][40][41][42][43]	10/88
o Crop 4 Rubarb						
-- Crop field trials	TEP		No		Yes[44]	10/88
o Crop 5 Spinach						
-- Crop field trials	TEP		No		Yes[45][46][47][48]	10/88
- Crop Group #5 - Brassica Leafy Vegetables						
o Crop 1 Broccoli						
-- Crop field trials	TEP		No		Yes[49][50]	10/88

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Fram for[2] Submissio
§158.240 - Residue Chemistry - Continued						
o Crop 2 Brussels sprouts						
-- Crop field trials	TEP		No		Yes 51/	10/88
o Crop 3 Cabbage						
-- Crop field trials	TEP		No		Yes 52/53/54/	10/88
o Crop 4 Cauliflower						
-- Crop field trials	TEP		No		Yes 55/	10/88
o Crop 5 Chinese Cabbage						
-- Crop field trials	TEP		No		Yes 56/	10/88
o Crop 6 Collards						
-- Crop field trials	TEP		No		No 57/	
o Crop 7 Kale						
-- Crop field trials	TEP		No		Yes 58/59/	10/88
o Crop 8 Kohlrabi						
-- Crop field trials	TEP		No		No 60/	
o Crop 9 Mustard Greens						
-- Crop field trials	TEP		No		No 61/	

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submissio
§158.240 - Residue Chemistry - Continued						
- Crop Group #6 - Legume Vegetables (Succulent or dried)						
o Crop 1 Beans (Succulent and dry)						
-- Crop field trials	TEP		No		Yes[62/63/64/65/]	10/88
-- Processed Food/Feed	EP		No		Yes[66/]	4/89
- Crop Group #7 - Fruiting Vegetables						
o Crop 1 Eggplant						
-- Crop field trials	TEP		No		No[67/]	
o Crop 2 Peppers						
-- Crop field trials	TEP		No		Yes[68/69/]	10/88
o Crop 3 Tomatoes						
-- Crop field trials	TEP				Yes[70/71/72/]	10/88
-- Processed Food/Feed	EP				Yes[73/]	4/89
- Crop Group #8 - Cucurbit Vegetables						
o Crop 1 Cucumbers						
-- Crop field trials	TEP		No		Yes[74/75/76/]	10/88
o Crop 2 Melons						
-- Crop field trials	TEP		No		Yes[77/78/79/80/]	10/88

GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
§158.240 - Residue Chemistry - Continued						
o Crop 3 Pumpkins						
-- Crop field trials	TEP		No		No[81]	
o Crop 4 Squash						
-- Crop field trials	TEP		No		No[82]	
- Crop Group #9 - Pome Fruit						
o Crop 1 Apples						
-- Crop field trials	TEP		No		Yes[83]	10/88
-- Processed Food/Feed	EP		No		Yes[84]	4/89
- Crop Group #10 - Stone Fruit						
o Crop 1 Apricots						
-- Crop field trials	TEP		No		Yes[85][86]	10/88
o Crop 2 Nectarines						
-- Crop field trials	TEP		No		No[87]	
o Crop 3 Peaches						
-- Crop field trials	TEP		No		Yes[88][89][90]	10/88

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
§158.240 - Residue Chemistry - Continued						
- Crop Group #11 - Small Fruits & Berries						
o Crop 1 Cranberries						
-- Crop field trials	TEP		No		Yes[91/92/93/]	10/88
o Crop 2 Grapes						
-- Crop field trials	TEP		No		Yes[94/]	10/88
-- Processed Food/Feed	EP		No		Yes[95/]	4/89
- Crop Group #12 - Tree Nuts						
o Crop 1 Almonds						
-- Crop field trials	TEP		No		Yes[96/97/98/]	10/88
- Crop Group #13 - Cereal Grains						
o Crop 1 Corn, Sweet						
-- Crop field trials	TEP		No		Yes[99/101/]	10/88
-- Processed Food/Feed	EP		No		Yes[100/]	4/89
- Crop Group #14 - Forage, Fodder & Straw of Cereal Grains						
o Crop 1 Corn forage, fodder & Silage						
-- Crop field trials	TEP		No		Yes[102/103/]	10/88

TABLE A

GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
§158.240 - Residue Chemistry - Continued						
- Crop Group #15 - Miscellaneous Commodities						
o Crop 1 Asparagus						
-- Crop field trials	TEP		No		Yes[104/][105/]	10/88
o Crop 2 Bananas						
-- Crop field trials	TEP		No		Yes[106/]	10/88
o Crop 3 Figs						
-- Crop field trials	TEP		No		Yes[107/][108/]	10/88
-- Processed Food/Feed	EP		No		Yes[109/]	4/89
o Crop 4 Papayas						
-- Crop field trials	TEP		No		Yes[110/]	10/88
o Crop 5 Seed, Seed Piece, planting stock, & propagation stock						
-- Crop field trials	TEP		No		Yes[111/]	10/88
o Crop 6 Tobacco						
-- Crop field trials	TEP		No		Yes[112/]	10/88
-- Processed Food/Feed	EP		No		Yes[113/]	4/89
171-4 - Magnitude of the Residue in Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites				Reserved[10/][114/]	

FOOTNOTES:

1/ Test Substance: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product; PAI = Pure active ingredient.

2/ These data have previously been requested in the Comprehensive Data Call In Notice issued April 1987. The time frame for submission of data is the same as required in the April 1987 Data Call In Notice. When number of months are provided, these are new data requirements which must be fulfilled in the number of months specified from the registrants receipt of this document.

3/ Refer to the Product Chemistry Data Requirement tables.

4/ The uptake, distribution, and metabolism of [^{14}C]maneb in root and tuber vegetables, pome fruit, fruiting vegetables, and cereal grain crops following a foliar application must be included. Sampling intervals through at least 21 days must be included. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate the terminal residues. Residue identities must be confirmed by a method such as GC, HPLC, and/or mass spectrometry. Data reflecting solvent extraction efficiency of maneb residues must also be represented. For the purpose of this Registration Standard, to ensure proper sequencing, the registrant should complete and submit all plant metabolism data to the Agency for review prior to initiation of residue field trials and processing studies.

5/ Representative samples from these tests must also be analyzed by enforcement methods to ascertain that these methods are capable of determining all metabolites of concern.

6/ Metabolism studies utilizing ruminants and poultry. Animals must be dosed for a minimum of three days with [^{14}C]maneb at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Data reflecting solvent extraction efficiency of maneb residues must also be represented.

7/ Representative samples from the above-described tests must also be analyzed by current enforcement methods to ascertain the validity of these methods.

8/ A confirmatory enforcement method must be developed and validated that is capable of differentiating between EBDC fungicides as well as other contaminants that degrade to CS_2. Residues of ethylenethiourea (ETU) and maneb per se in/on crop samples must be subjected to analysis by the multiresidue methods published in PAM Vol. I. Protocols for methods I, II, III, and IV are available from NTIS. If tolerances are established for residues in livestock products, then these products must also be subject to multiresidue methodologies.

9/ To support crop residue data, storage stability studies must be conducted on both weathered samples (maneb) and fortified frozen samples (maneb, metabolites and ETU) of one representative crop from each crop grouping (40 CFR 180.34) on which registered uses of maneb exist. Analyses of each crop must be conducted over a time period that includes the time interval that the raw agricultural commodity is held in frozen storage prior to the crop residue analysis. To support residue data on processed commodities, fortified storage stability data are required for all processing studies submitted to the Agency. Analyses must be conducted over a time period that includes the frozen storage of the raw agricultural commodity prior to processing and each processed commodity prior to the residue analysis. Protocols for these studies must be submitted to and approved by the Agency prior to initiating the studies.

(a) Storage stability data using weathered samples. Data are required on the parent compound, maneb, in which crop samples field treated with a typical end use product are frozen immediately upon harvesting. The integrity of the samples must be maintained by freezing. The samples must be analyzed for maneb on the day they arrive at the analytical laboratory, and then stored frozen and analyzed periodically for maneb during the time intervals specified in the Agency approved protocol.

(b) Storage stability data using fortified samples. Data are required on maneb, ETU, and metabolites in which a group of untreated samples of raw agricultural commodities and processed crops are fortified (spiked) with only maneb (pure active ingredient), another group of samples is fortified with only ETU, and other groups are fortified individually with each additional metabolite. Immediately after fortification, the samples fortified with maneb must be analyzed for maneb and ETU; samples fortified with ETU must be analyzed for only ETU; and samples fortified with other metabolites must be analyzed for only the metabolite with which the sample was fortified. Sample integrity must be maintained by freezing, and analyses for maneb, ETU, and metabolites must be conducted periodically during the time intervals specified in the Agency approved protocol.

10/ Storage stability data for livestock/poultry feeding studies. If cattle and poultry feeding studies are required (see footnote 114), fortified storage stability studies will be required on all animal commodities (i.e., tissues, milk and eggs) for which residue data are submitted to the Agency. Analyses must be conducted over a time period that includes the time interval that each commodity is held in frozen storage prior to residue analyses.

11/ The Agency has considered possible validation of earlier submitted data, but has concluded that validation of existing crop residue, processing, and animal commodity samples would not be acceptable due to the highly variable and in many instances unknown conditions (e.g., ambient and freezer temperatures, sample handling, preparation and extraction parameters prior to analyses) which may have existed at the residue laboratories generating the residue data which were evaluated. The available storage stability data demonstrate that maneb and ETU are not stable under the storage conditions associated with many of the existing residue studies. The Agency has concluded that new frozen storage stability data on Maneb and ETU must be generated (refer to footnote 9) concurrently with the required crop residue, processing, and animal commodity studies on these chemicals.

12/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on carrots following multiple foliar applications of a WP or FlC formulation at 2.4 lb ai/A and, in a separate test, a D formulation at 2.7 lb ai/A. Aerial and ground equipment must be represented in separate tests. The first application must be made when the plants are 6 weeks old and be repeated at 7-day intervals until the day of harvest. The registrant must propose a maximum seasonal application rate or maximum number of applications per season. Required data must reflect the proposed maximum rate. Tests must be conducted in CA(66%), MI(10%) and TX(12%) which collectively account for 88% of U.S. carrot production (Agricultural Statistics, 1985, p. 151).

13/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on carrots harvested on the day of the last of several foliar applications of an 80% WP at 2.96 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 5967-5138.

14/ The available data for the 80% WP indicate that tolerance-exceeding residues will occur following use at the registered rate. Upon generation of the data requested above, the registrant may propose a higher tolerance or amend the labels (propose a PHI, maximum seasonal application rate, and/or decrease the single application rate). If the label is amended, data must support these amendments.

15/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on potatoes following multiple foliar applications (using ground and aerial equipment in separate tests) of: (i) a D formulation at 3.3 lb ai/A; (ii) a FlC or WP formulation at 3.2 lb ai/A; and (iii) a WP/D formulation at 3.3 lb ai/A. The registrant must propose a maximum seasonal application rate or maximum number of applications p season. Required studies must reflect this propose maximum rate. Required studies must be conducted in CA(6%), ID(25%), ME(7%), ND(6%), and WA(16%), which collectively produce 60% of U.S. potatoes (Agricultural Statistics, 1984, p. 165).

16/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on potatoes harvested 0-days following the last of several foliar applications of a 80% WP at 4 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 5967-5138.

17/ Data must be submitted depicting maneb, ETU, and other residues of concern in potato chips, granules, wet peel, and dry peel processed from potatoes bearing measurable weathered residues. If residues concentrate during processing appropriate food/ feed additive tolerances must be proposed.

18/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on sugar beet roots following five applications of, in separate tests, a WP, WP/D, or FlC formulation at 2.6 lb ai/A and in a separate test a D formulation at 1.2 lb ai/A; use of aerial and ground equipment must be represented. The first application should begin at the normal time of disease development and be repeated at 7- to 10-day intervals until 10 days prior to harvest. Studies must be conducted CA(19%), ID(17%), MN(23%), and ND(11%), which collectively account for 70% of U.S. sugar beet production Agricultural Statistics, 1984, p.76).

19/ Data must be submitted depicting maneb, ETU, and other residues of concern in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearing measurable, weathered residues. If concentration of residues occurs during processing, the registrant must propose appropriate food/feed additive tolerances.

20/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on sugar beets harvested on the day of the last of several foliar applications of the 5.6% D at 1.56 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 11169-50024.

21/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on sugar beets harvested 10 days following the last of several foliar applications of the 6% D at 2.58 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registant may elect to cancel the state use permitted under EPA Reg. No. 7001-7772.

22/ No data were submitted pertaining to maneb residues in or on turnip roots. However, no residue data are required The data requested for sugar beet roots will be translated to turnips since the registered uses on sugar beets are similar to those for turnips.

23/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on sugar beet tops harvested 14 days following the last of five foliar applications (using ground and aerial equipment in separate tests) of a WP, WP/D or FlC formulation at 2.6 lb ai/A (in separate tests). Studies must be conducted in CA(19%), ID(17%), MN(23%), and ND(11%), which collectively account for 70% of U.S. sugar beet production (Agricultural Statistics, 1984, p. 76).

24/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on sugar beet tops harvested on the day of the last of several foliar applications of the 5.6% D formulation at 1.56 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 11169-50024.

25/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on sugar beet tops harvested 10 days following the last of several foliar application of the 6% D formulation at 2.58 lb ai/A. Applications with aerial and ground equipment must be represented in separate tests. Tests must be conducted in CA. Alternatively the registrant may elect to cancel the state use permitted under EPA Reg. No. 7001-7772.

26/ The registrants must also propose label restrictions for the 5.6% D (EPA Reg. No. 11169-50024) and 6% D formulation (EPA Reg. No. 7001-7772) limiting the maximum number of applications and maximum seasonal use rate and specifying a minimum interval between applicaitons, and specifying a minimum PHI for the 5.6% D.

27/ No data were submitted pertaining to maneb residues in or on turnip tops. However, no residue data are required. The data required for sugar beet tops will be translated to turnip tops since the registered uses on sugar beets are similar to those for turnips. In addition, the registrant must propose a maximum seasonal application rate or maximum number of applications per season consistent with the submitted residue data.

28/ Data must be submitted depicting maneb residues of concern in or on green and dry bulb onions harvested on the day after the final application of the following full season treatment schedule: a soil application with the seed, of the 4 lb/ gal FlC formulation at 2.4 lb ai/A, followed by multiple foliar applications of a registered D formulation at 3 lb ai/A and, in a separate test, a WP or FLC at 3.0 lb. ai/A. Foliar applications must be made using both ground and aerial equipment in separate tests. The registrant must propose a maximum seasonal application rate or maximum number of applications per season. Required studies must reflect the proposed maximum rate. Tests on green onions must be conducted in AZ(15%) CA(36%), and TX(23%) which collectively account for 74% of U.S. green onion acreage; tests with bulb onions must be conducted in CA(23%), CO(8%), MI(7%), NY(11%), and TX(20%), which collectively account for 69% of U.S. bulb onion acreage (1982 Census of Agriculture, Vol. 1, Part 51, pp. 346-347).

29/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on onions harvested on the day of the last of several foliar applications of a 80% WP at 2.96 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA. Reg. No. 5967-5138.

30/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on onions harvested 4-days following the last of several foliar applications of the 80% WP at 2 lb ai/100 gal (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 9782-3633.

31/ Available data indicate that tolerance-exceeding residues may occur following foliar applications of the WP. Upon receipt of the requested data, a proposal for a tolerance increase or label modification may be necessary.

32/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on celery 14 days following the last of multiple foliar applications of a WP or FlC formulation at 2.4 lb ai/A, and, in a separate test, a D formulation at 2.7 lb ai/A. Separate studies must be made using aerial and ground equipment. Tests must be conducted in CA(68%), FL(22%) and MI(7%) to provided adequate geographic representation (Agricultural Statistics, 1984, p. 156). The registrant must propose a maximum seasonal application rate or maximum number of applications per season. Requirement studies must reflect this maximum rate.

33/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on celery harvested 14-days following the last of several foliar applications of the 80% WP at 3.2 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 5967-5138.

34/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on celery harvested on the day of the last of several foliar applications of a 42.5% FlC at 2.7 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 9859-9146.

35/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on celery harvested 0-days following the last of several foliar applications of the 3.2% D at 1.6 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 9782-3634.

36/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on celery harvested 0-days following the last of several foliar applications of the 5.6% D at 2.8 lb ai/A (aerial and ground equipment must be represented in separate tests. Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 1202-5059.

37/ Note that tolerance-exceeding residues occur following foliar treatments with the 80% WP. Upon generation of all requested data, the registrant may either propose a higher tolerance or propose label revisions to reduce residues to subtolerance levels, provided that data support such revisions.

38/ No data were submitted pertaining to maneb residues of concern in or on endive. However, no data are required. The requested data for lettuce will be translated to endive since the registered uses are identical for the two crops.

39/ Data must be submitted depicting maneb residues of concern in or on lettuce 10 days following multiple foliar applications (in separate tests) of a WP or F1C formulation at 2.4 lb ai/A and a D formulation at 3.2 lb ai/A. Studies must reflect ground and aerial applications (in separate tests) and must be conducted in CA which accounts for 69% of U.S. lettuce production (Agricultural Statistics, 1984, p. 160). The registrant must propose a maximum seasonal application rate or maximum number of applications per season; this proposed maximum rate must be reflected in the studies submitted.

40/ Data must be submitted from a test conducted in CO depicting maneb, ETU, and other residues of concern in or on lettuce harvested 7 days following the last of multiple foliar applications of the 5% D MAI formulation at 1.25 lb ai/A. Alternatively, the registrant may elect to cancel the state use permitted by EPA Reg. No. 960-3828.

41/ Data must be submitted from a test conducted in CA depicting maneb, ETU, and other residues of concern in or on lettuce harvested on the day of the last of a series of foliar applications of a D formulation at 3.08 lb ai/A. Alternatively, the registrant may elect to cancel the state use permitted by EPA Reg. Nos. 1202-5059 and 6023-3042.

42/ Data must be submitted from a test conducted in FL depicting maneb, ETU, and other residues of concern in or on lettuce harvested on the day of the last in a series of foliar applications of the 7% D MAI formulation at 2.1 lb ai/A. Alternatively, the registrant may elect to cancel the state use permitted by EPA Reg. No. 14775-8738.

43/ Data must be submitted depicting residues of concern in or on lettuce harvested on the day of the last of several foliar applicatio of the 4.8% D formulation at 2.4 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted by EPA Reg. No. 6023-3042.

44/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on greenhouse-grown rhubarb following the last of four foliar applications (made at 7-day intervals) of the 80% WP or an F1C formulation at 1.6 lb ai/100 gal. The PHI must reflect that proposed by the registrant. Studies must be conducted in MI.

45/ Data must be submitted depicting maneb residues of concern, including ETU, in or on spinach 10 days following the last of multiple foliar applications of a WP or F1C formulation at 2.4 lb ai/A, and, in a separate test, a D formulation at 2.7 lb ai/A. Both aerial and ground equipment must be employed (in separate tests) and required studies must be conducted in CA(24%), CO(5%), NJ(6%), TN(4%), and TX(25%) which collectively account for 64% of U.S. spinach acreage (1982 Census of Agriculture, Vol. 1 Part 51, p. 352).

46/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on spinach harvested 7 days following the last of several foliar applications of the 5.6% D formulation at 2.5 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 1202-5059.

47/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on spinach harvested 7 days following the last of several foliar applications of the 4.8% D formulation at 2.4 lb ai/A (aerial and ground equipment must be used in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 6023-3042.

48/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on spinach harvested 7 days following the last of several foliar applications of the 6% D formulation at 2.7 lb ai/A (aerial and ground equipment must be used in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 7001-7772.

49/ Data must be submitted depicting maneb residues of concern, including ETU, in or on broccoli resulting from the following fullseason application schedule: multiple soil applications to the plant bed of a WP formulation at 1.4 lb ai/100 gal followed by multiple foliar applications (by aerial and ground equipment in separate tests) of a WP, WP/D, or FlC formulation applied as spray at 3.2 lb ai/A and a D or WP/D formulation as a dust at 3.3 lb ai/A (each formulation in a separate test). These tests must be conducted in CA(82%) to provide adequate geographic representation (acreage percentage is from 1982 Census of Agriculture, Vol. 1, Part 51, pp. 337-338).

50/ The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect residues resulting from such usage.

51/ No data were submitted pertaining to residues of maneb in or on Brussels sprouts. However, no data are required; broccoli data may be translated to Brussels sprouts since the registered uses on the two crops are similar. The registrant must propose a maximum seasonal application rate or maximum number of applications per season. Translated data must reflect this maximum rate. It should be noted that translated data may not be used to support a crop group tolerance.

52/ Data must be submitted depicting maneb residues of concern, including ETU, in or on cabbage following multiple foliar applications of a WP, WP/D, or FlC formulation at 1.8 lb applied as a spray and, in separate tests, a D or WP/D formulation as a dust at 2.6 lb ai/A. Ground and aerial applications must be represented in separate tests. Studies must be conducted in CA(8%), FL(16%), MI(3%), NJ(3%), NY(15%), NC(5%), OH(3%), TX(16%), and WI(1%) which together account for 70% of U.S. cabbage acreage (1982 Census of Agriculture, Vol. 1, Part 51, pp. 338 and 339).

53/ The registrant must propose a maximum seasonal application rate or maximum number of applications per season. Required studies must reflect residues resulting from application at the maximum rate.

54/ Data must be submitted depicting maneb ETU, and other residues of concern in or on cabbage harvested 7 days following the last of several foliar applications of a 42.5% FlC at 2.7 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 9859-9146.

55/ No data were submitted pertaining to residues of maneb in or on cauliflower. However, no data are required; broccoli data may be translated to cauliflower since registered uses on the two crops are similar. The following information is required: The registrant must propose a maximum seasonal application rate or maximum number of applications per season. Translated data must reflect this maximum rate.

56/ Data must be submitted from tests conducted in CA depicting maneb, ETU, and other residues of concern in or on Chinese cabbage following multiple foliar applications (using ground equipment) of the 80% WP formulation at 1.2 lb ai/A. Samples must be collected 7 days following the last treatment.

57/ No data were submitted in support of the tolerance for maneb residues in or on collards. However, no data are required. The required data for spinach will be translated to collards since the use directions are similar (see section on spinach for details of data requirements).

58/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on kale following multiple foliar applications (using ground and aerial equipment in separate tests) of a D formulation and, in a separate test, a WP formulation at 2.4 lb ai/A. Tests must be conducted in CA(13%), FL(10%), MD(6%), NJ(5%), PA(6%), TX(13%), and VA(13%) which collectively account for 66% of U.S. kale acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 345) in order to provide adequate geographic representation.

59/ The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect this maximum rate.

60/ No data were submitted pertaining to residues of maneb in or on kohlrabi. However, no data are required; broccoli data may be translated to kohlrabi since registered uses on the two crops are similar. The following information is required: The registrant must propose a maximum seasonal application rate or maximum number of applications per season. Translated data must reflect this maximum rate.

61/ No data were submitted in support of the tolerance for maneb residues in or on mustard greens. However, no data are required. The required data for spinach will be translated to mustard greens since the use directions are similar (see section on spinach for details of data requirements).

62/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on dried beans harvested on the last day of multiple foliar applications (at-4 day intervals) of a WP, WP/D, or FlC formulation and in separate tests a D or WP/D formulation (applied as a dust) at 2.8 lb ai/A. These tests must be performed using aerial and high and low volume ground equipment. Dried bean tests must be conducted in MI(29%), CA(15%), NE(14%), CO(11%) and ND(11%), which represent ca. 80% of 1983 U.S. dried bean production (data from Agricultural Statistics, 1984, p. 256).

63/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on succulent beans harvested 4 days after the last of several foliar applications (by aerial and ground equipment) of the 80% WP formulation at 2.8 lb ai/A. Snap bean tests should be conducted in the states of WI(36%), OR(21%), NY(15%), and MI(7%) which collectively represent CA 80% of 1983 U.S. snap bean production (data from Agricultural Statistics, 1984, p. 151). Lima bean tests must be conducted in CA(58%), WI(9%), and DE(7%), which represent 74% of 1977 U.S. lima bean production (G.W. Ware and J.P. McCollum, 1980, Producing Vegetable Crops, Interstate Printers & Publishers, Inc., Danville IL, 508 pp.).

64/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on beans harvested 3 days following the last of three foliar applications of the 6% D formulation at 1.8 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in OR. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 1871-8934.

65/ The registrant(s) must propose a maximum number of applications per season or maximum seasonal use rate for beans (succulent and dry); requested data must reflect the proposed maximum rate.

66/ Residues must be determined in cannery waste (of dried and succulent beans) obtained from beans bearing measurable weathered residues; if residues concentrate in cannery waste, an appropriate feed additive tolerance must be proposed.

67/ No data were submitted pertaining to residues of maneb in or on eggplant. However, no data are required since studies requested for tomatoes may be translated to eggplant because registered uses on the two crops are similar.

68/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on peppers following multiple foliar applications of a WP or an FlC fomulation at 3 lb ai/A using aerial and ground equipment and, in separate tests, a D formulation at 3 lb ai/A using aerial and ground equipment. The registrant must propose a PHI and a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect these proposed uses. Studies must be conducted in CA(18%), FL(23%), NC(10%), and TX(16%) (acreages follow state abbreviations parenthetically) which collectively account for 67% of U.S. pepper acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 350) in order to provide adequate geographic representation.

69/ Available data indicate that tolerance-exceeding residues will occur following application of the WP at the maximum registered rate. Upon generation of the requested data, the registrant must propose a tolerance increase or modify the labels to result in subtolerance residues. Label revisions must be supported by residue data.

70/ Data must be submitted depicting maneb residues of concern, including ETU, in or on tomatoes 5 days following multiple foliar applications (using ground and aerial equipment in separate tests) of a WP or FlC at 3.3 lb ai/A and a D formulation at 3.4 lb ai/A. Tests must be conducted in FL, CA, MI, and TX which produce 50%, 29%, 1%, and 1%, respectively (totaling 81%), of U.S. tomatoes (production percentages are from Agricultrual Statistics, 1984, p. 173) in order to provide adequate geographic representation. The registrant must propose a maximum number of application per season or a maximum seasonal application rate. Submitted studies must reflect the proposed use.

71/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on tomatoes harvested 5 days following the last of several foliar applications of the 80% WP formulation at 4 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 5967-5138.

72/ Data must be submitted from tests conducted in FL depicting maneb, ETU, and other residues of concern in or on tomatoes harvested 3 days following the last of multiple foliar applications of a D formulation at 2.4 lb ai/A, and in separate tests, a WP formulation at 2 lb ai/100 gal (tomatoes harvested on the day of the final application). Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. Nos. 9169-5295, 9169-5292, and 7478-8009. The application rate(s) associated with EPA Reg. Nos. 7478-8035 and 9782-3634 must be specified. Data must be submitted from a study conducted in CA depicting maneb, ETU, and other residues of concern in or on tomatoes harvested on the day of the last of multiple foliar applications of a D formulation at 2.5 lb ai/A. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. Nos. 1202-5059 and 6023-3042.

73/ A tomato processing study must be conducted and submitted whereby residues of maneb, ETU and other residues of concern are determined in wet pomace, dry pomace, puree, catsup, and juice processed from tomatoes bearing detectable field-weathered residues.

74/ Data must be depicting maneb, ETU, and other residues of concern in or on cucumbers harvested 5 days following the last of multiple foliar applications (using ground and aerial equipment in separate tests) of a D formulation at 3 ai/A and a WP (or FlC) formulation at 3 lb ai/A. Tests must be conducted in CA(6%), FL(12%), MI(15%), NC(14%), SC(5%), TX(11%), and VA(5%) which collectively account for 68% of U.S. cucumber acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 342-343). The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect this proposed maximum rate.

75/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on cucumbers harvested on the day of the last of the several foliar applications of the 4.8% D fomulation at 2.4 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 6023-3042.

76/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on cucumbers harvested on the day of the last of the several foliar applications of the 42.5% FlC formulation at 2.7 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 9859-9146.

77/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on cantaloupes, honeydew melon, or watermelon harvested 5 days following the last of multiple foliar applications (using ground and aerial equipment in separate tests) of a D formulation and a WP formulation at 2.4 lb ai/A. The registrant must propose a PHI and a maximum seasonal application rate or maximum number of applications per season. Required studies must reflect these proposals. Tests must be conducted in CA, GA, FL, and TX, which collectively account for 76% of U.S. cantaloupe acreage, 81% of U.S. honeydew melon acreage, and 63% of U.S. watermelon acreage (1982 Census of Agriculture, Vol. 1, Part 51, pp. 339, 345, 356, 357, respectively).

78/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on melons harvested on the day of the last of several foliar applications of the 4.8% D formulation at 2.4 lb ai/A (aerial and ground equipment must be used in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 6023-3042.

79/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on watermelons harvested 5 days following the last of several foliar applications of the 80% WP formulation at 5 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg. No. 9782-3633.

80/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on watermelons harvested on the day of the last of several foliar applications of the 42.5% FlC formulation at 2.7 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel the state use permitted under EPA Reg.No. 9859-9146.

81/ The data submitted were inadequate to support the established tolerance for maneb residues in or on pumpkins. However, no additonal data are required. The data requested for melons may be translated to pumpkins since the registered uses on the two crops are similar (refer to the melons section for details of data requirements).

82/ The data submitted are inadequate to support the established tolerance for maneb residues in or on squash. However, no additonal data are required since requested residue data for cucumbers may be translated to summer squash, and data requested for melons may be translated to winter squash.

83/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on apples 15 days following the last of multiple foliar aerial and ground applications of a WP or FlC formulation at 8.4 lb ai/A in AR, DE, IL, IN, KS, KY, MD, MO, NJ, OH, PA, SC, TN, VA, and WV, and 30 days following the last of these applications in all other states. The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect this proposed maximum rate. Tests must be conducted in CA(6%), MI(9%), NY(12%), VA(6%), and WA(36%), which collective produce 69% of U.S. apples (Agricultural Statistics, 1985, p. 186) in order to provide adequate geographic representation.

84/ To determine if concentration of residues or conversion of maneb to ETU occurs in dry pomace and juice during processing, the registrant must conduct and submit appropriate processing studies. Food/feed additive tolerances may need to be proposed pending receipt of adequate storage stability data and field residue data determining the residues in the raw agricultural commodity.

85/ Data must be submitted depicting residues of maneb, its metabolite ETU, and other residues of concern in or on apricots harvested 14 days following multiple foliar applications of a WP formulation at 8 lb ai/A; and (in a separate test) a D formulation at 8.4 lb ai/A. Studies must be done using ground and aerial equipment in separate tests. CA, which produces 97% of U.S. apricots, must be the test state (Agricultural Statistics, 1985, p. 191).

86/ The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect this proposed maximum rate.

87/ No acceptable data were submitted in support of the established tolerance for residues of maneb in or on nectarines. However, no data are required; the requested data for peaches may be translated to nectarines since the registered uses of maneb on nectarines are identical to those on peaches.

88/ Data must be submitted depicting residues of maneb, its metabolite ETU, and other residues of concern in or on peaches 2 days following the last of multiple foliar applications of (in separate tests) a WP (or a FlC) formulation at 8.0 lb ai/A, and a D formulation at 5.6 lb ai/A. Separate tests must reflect use of ground and aerial equipment. Tests must be conducted in CA(56%) and SC(18%), which together produce 74% of U.S. peaches, in order to provide adequate geographic representation (production figures are from Agricultural Statistics, 1985, p. 21). The registrant must propose a maximum seasonal application rate or a maximum number of applications per season.

Required studies must reflect this proposed maximum rate.

89/ Data must be submitted from tests conducted in CA depicting maneb, ETU, and other residues of concern in or on peaches harvested 14 days following the last of a series of foliar applications of the 80% WP formulation at 10 lb ai/A. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 5967-5138.

90/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on peaches harvested 2 days following the last of several foliar applications of a 6% D formulation at 6 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 7001-7772.

91/ Residue data must be submitted depicting maneb, ETU, and other residues of concern in or on cranberries harvested 30 days after the last of multiple foliar applications, in separate tests, of a registered WP (or FlC) and a D formulation at 6 lb ai/A. Applications must be initiated at midbloom, and repeated at 10-day intervals, up to 4 weeks after midbloom. These tests must be conducted in WI(42%) and MA(41%), which collectively represent ca. 83% of the U.S. cranberry production (1982 Census of Agriculture, Vol. 1, Part 51, p. 321).

92/ Residue data must be submitted for maneb, ETU, and other residues of concern in or on cranberries harvested 30 days after application of a FlC (or WP) at 5.6 lb ai/A with treatment initiated after midbloom, and repeated between July 10 and 20, August 1 and 10, and August 10 and 25. Do not apply later than 4 weeks after midbloom. These tests must be conducted in OR and WA. Each of the above mentioned tests must be conducted using separate aerial and ground (high and low volume) equipment.

93/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on cranberries harvested 4 weeks following the last of several foliar applications of the 5.6% D formulation at 4.7 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternately, the intrastate label EPA Reg. No. 1202-5059 may be cancelled.

94/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on grapes harvested 7 days after the last of multiple foliar applications (in separate tests) of a registered WP, WP/D, or FlC at 4.0 lb ai/A and a D formulation at 1.5 lb ai/A, respectively. Each of these tests must be preceded by three applications of an FlC or WP formulation at 4.0 lb ai/A to be applied just before bloom, just after bloom, and 10 days after bloom. The requested tests must be conducted utilizing separate aerial and high- and low-volume ground equipment. Tests must be performed in CA, which represents Ca. 90% of the U.S. grape production (Agricultural Statistics, 1985, p. 207).

95/ Since concentration of maneb and/or conversion of maneb to ETU may occur in dry pomace, raisins, raisin waste, and grape juice, the registrant must conduct appropriate processing studies. If residues concentrate, appropriate food/feed additive tolerances must be proposed.

96/ Data must be submitted depicting maneb, ETU and any other residues of concern in or on almond nuts and hulls following multiple foliar applications of WP, WP/D, or FlC formulation at 6.4 lb ai/A. Studies must use ground and aerial equipment in separate tests. These tests must be conducted in CA, which produces 99% of U.S. almonds (1982 Census of Agriculture Vol. 1, Part 51, p. 367).

97/ Since almond hulls are a raw agricultural commodity, and feeding restrictions are considered impractical, the registrant must propose a tolerance for maneb residues in or on almond hulls.

98/ The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect the proposed maximum rate.

99/ Data must be submitted depicting residues of maneb, its metabolite ETU, and other residues of concern in or on sweet corn (kernels plus cob with husks removed) following multiple foliar applications of a D formulation and a WP or FlC formulation at 2.3 lb ai/A. Separate tests must reflect use of ground and aerial equipment. The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect this proposed rate. Tests must be conducted in FL(8%), IL(6%), NY(8%), MN(11%), WA(8%), and WI(19%) which collectively produce 60% of U.S. sweet corn (Agricultural Statistics, 1985, p. 156).

100/ Data must be submitted depicting residues of maneb, its metabolite ETU and other residues of concern in cannery waste processed from sweet corn bearing measurable weathered residues. If residues concentrate during processing, the registrant must propose an appropriate feed additive tolerance.

101/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on sweet corn harvested on the day of the last of several foliar applications of the 80% WP formulation at 2.5 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 9782-93633.

102/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on forage of sweet corn harvested on the day of the last of several foliar applications of the 80% WP formulation at 2.5 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in FL. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 9782-93633.

103/ Data must be submitted depicting residues of maneb, its metabolite ETU, and other residues of concern in or on sweet corn forage following multiple foliar applications of a D formulation at 2.4 lb ai/A. Separate tests must reflect use of ground and aerial equipment. The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect this proposed rate. Tests must be conducted in FL(8%), NY(8%), MN(11%), WA(8%), and WI(19%) which collectively produce 54% of U.S. sweet corn (Agricultural Statistics, 1985, p. 156).

104/ Data must be submitted depicting maneb, ETU and other residues of concern in or on asparagus harvested from plants treated with multiple post-harvest foliar applications of a WP, WP/D, or FlC formulation at 2.4 lb ai/A. The registrant must propose a tolerance for residues of maneb in or on asparagus and a maximum seasonal application rate. Required residue data must reflect this proposed maximum rate. Tests must be conducted in CA(36%), MI(20%), and WA(31%) which collectively account for 87% of U.S. asparagus acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 335).

105/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on asparagus harvested on the day of the last of several foliar applications of the 5.6% D at 2.35 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 1202-5059.

106/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on banana fruit (whole) and banana pulp following multiple foliar applications of the 80% WP formulation or the 4 lb FlC formulation at 4 lb ai/A. Use of ground and aerial equipment must be represented in separate tests. Tests must be conducted in HI which produces 82% of U.S. bananas (1982 Census of Agriculture, Vol. 1, Part 51, p. 360). The registrant must propose a maximum number of applications per season or maximum seasonal application rate. Required studies must reflect the proposed maximum rate. If maneb products are used on bananas in countries exporting fruit to the U.S., then copies of product labels and supporting residue data must be submitted.

107/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on figs harvested 10 days after a single application of a WP (or FlC) formulation at a spray concentration of 0.5-0.6 lb ai/100 gal. Tests must be conducted in CA, which accounts for about 99% of U.S. fig acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 361).

108/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on figs harvested 10-days following a single foliar application of the 80% WP formulation at 2.4 lb ai/A (aerial and ground equipment must be represented in separate tests). Tests must be conducted in CA. Alternatively, the registrant may elect to cancel this state use permitted under EPA Reg. No. 5967-50136.

109/ Data must be submitted depicting residues in dried figs processed from figs bearing measurable, weathered residues. If residues concentrate in this processed commodity, an appropriate food additive tolerance must be proposed.

110/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on papayas resulting from multiple foliar applications of the 4 lb/gal FlC formulation at 2.4 lb ai/A. Use of ground and aerial equipment must be reflected in separate tests. The registrant must propose a maximum seasonal use rate or maximum number of applications per season, as well as a PHI. Required tests must reflect these proposals. Studies must be conducted in HI which accounts for 99% of U.S. papaya acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 363).

111/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on barley, corn (other than sweet corn), cotton flax, oats, peanuts, pineapple, rice, rye, sorghum, soybeans, sunflower, and wheat resulting from seed treated with maneb according to the label directions of the product at the maximum permissible use rate (in some cases, the maximum rate is present on a multiple active ingredient formulation label). Samples of all raw agricultural commodities for each crop must be collected at the shortest interval after planting in which they could be used for food or feed purposes. Tolerances must be proposed that reflect either the maximum expected residue levels or, if no measurable residues are detected, the limit of detection of the analytical method. All required processing studies must utilize raw agricultural commodities bearing measurable, weathered residues. Given the long PHI for asparagus crowns or caprifigs, no residue data are required for these racs.

112/ Data must be submitted depicting maneb, ETU, and other residues of concern in or on green, freshly harvested tobacco receiving the following full-season treatment schedule: (i) multiple foliar plant bed treatments of a WP or FlC formulation at 3.2 lb ai/100 gal (5 gal/100 sq yards) and in a separate test, a D formulation at 0.14 lb ai/100 sq. yards followed by (ii) multiple foliar applications (to plants set in field) by air and, in separate tests, by ground equipment of a WP, WP/D or FlC formulation at 3.2 lb ai/A and, in a separate test, a D formulation at 2.1 lb ai/A. The registrant must propose a maximum seasonal application rate or a maximum number of applications per season. Required studies must reflect these rates.

113/ If residues in freshly harvested green tobacco exceed 0.1 ppm, data depicting residues in or on dried or cured tobacco will be required. If residues in or on dried or cured tobacco exceed 0.1 ppm, pyrolysis products derived from the active ingredient must be characterized and the level of residue in smoke must be quantified. ($[^{14}C]$-maneb must be used for identification of pyrolysis products.

114/ Presently, the nature of the residue in animals is not adequately understood. On receipt of the data concerning nature of the residue in animals, the need for tolerances for residues in animal products will be reassessed with consideration for any additional metabolites of toxicological concern.

115/ Data have been submitted by the Maneb Task Force and are currently under review.

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use[2] Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.290 - Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No		Yes	1/88[11]
	ETU	A,B	Yes	40466103	No	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B	No		Yes	1/88[11]
	ETU	A,B	Yes	40466102	No	
161-3 - On soil	TGAI or PAIRA	A	No		Yes	1/88[11]
	ETU	A	Yes	40466101	No	
161-4 - In Air	TGAI or PAIRA	A	No		Reserved[4]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No		Yes	6/89[11]
	ETU	A,B	No		Yes	6/89
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	00163335	No[5]	
	ETU	A	No		Yes	6/89
162-3 - Anaerobic Aquatic	TGAI or PAIRA		Yes	00163335	No[6]	

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use[2] Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.290 - Environmental Fate - Continued						
162-4 - Aerobic Aquatic	TGAI or PAIRA	A	No		Yes[6]	6/89
	ETU	A	No		Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	No		Yes	4/88[11]
	ETU	A,B	No		Yes	4/88[11]
163-2 - Volatility (Lab)	ETU	A	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No		Reserved[8]	
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No		Yes	6/89
	ETU	A,B	No		Yes	6/89
164-2 - Aquatic (Sediment)	TEP	A	No		Yes[6][6]	7/89
	ETU	A	No		Yes	27 Months
164-3 - Forestry	TEP	-	No		No	
164-5 - Soil, Long-term	TEP	A,B	No		Yes[9][9]	50 Months
	ETU	A,B	No		Yes	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[7]	7/90

GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Patterns[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[3]
§158.290 - Environmental Fate - Continued						
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved[10]	
165-3 - Irrigated Crops	TEP	A	No		Yes[6]	7/90
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes[7]	4/88[13]
	ETU	A,B	No		Yes	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	-	-		No	
Special Studies						
Small Scale Retrospective Ground-Water Monitoring Study	Maneb	A,B	No		Yes[12]	3 Years from Agency's acceptance of protocol which is due Sept. 1988.
	ETU	A,B	No		Yes[12]	

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[1] Composition: TGAI = Technical Grade of the Active Ingredient, PAIRA = Pure Active Ingredient, Radiolabeled, TEP = Typical End-Use Product.

[2] Use Patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food;

[3] These data have previously been requested in the Comprehensive Data Call In Notice issued April 1987. The time frame for submission of data is the same as required in the April 1987 Data Call In Notice. When number of months are provided, these are new data requirements which must be fulfilled in the number of months specified from the registrant's receipt of this document.

[4] Maneb has low volatility. Volatility data on ETU is not available. ETU may volatalize but

is unlikely to degrade in air since it does not degrade under sunlight in water and on soil.

5/ The anaerobic aquatic data will satisfy this requirement.

6/ Maneb has a registered cranberry use.

7/ Data required on both maneb and ETU. Emphasis must be placed on ETU.

8/ Reserved pending results of laboratory volatility data and review of toxicological and reentry issues.

9/ Prospective monitoring studies and field leaching studies addressing ETU and maneb is optional as replacement for the conventional long-term field dissipation study. This study would trace the movement of ETU through the soil profile in soil pore water in the vadose zone and in shallow groundwater. Interim results of this study must be submitted for assessment 6 months after the studies are initiated. Whether the registrant select to generate the conventional long-term field study or the prospective study, an adequate study must be submitted to the Agency within 50 months from registrant's receipt of this Registration standard.

10/ Reserved pending results of confined rotational crop study.

11/ Data have recently been submitted and are under review.

12/ A small-scale retrospective ground-water monitoring study on maneb/ETU was required in the April 25, 1988 Data Call In Notice. Progress reports are due semi-annually, the first one is due November, 1988.

13/ Registrant has requested a waiver of this data requirement which is currently under review by the Agency.

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Date Requirement	Test[1] Substance	Use[2] Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for[3] Submission
§158.340 - Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,H	Yes	00129749	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,H	Yes	00128936	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,H	Yes	00129750	No	
81-4 - Eye Irritation - Rabbit	TGAI	A,B,H	Yes	00128937	No	
81-5 - Dermal Irritation - Rabbit	TGAI	A,B,H	Yes	00128938	No	
81-6 - Dermal Sensitization - Guinea pig	TGAI	A,B,H	Yes	00141264	No	
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,H	No		No 4/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and	TGAI	A	No		No 5/	
- Non-rodent (Dog)	TGAI	A	Yes	00129980	No	
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,H	No		Yes	9/88
82-3 - 90-Day Dermal - Rabbit	TGAI		No		No 6/	
82-4 - 90-Day Inhalation Rat	TGAI	A,B,H	Partially	00162084	Yes 7/	12/88

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use[2] Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.340 - Toxicology - Continued						
82-5 - 90-Day Neurotoxicity: - Dog	TGAI	A,B,H	No		No 4/	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species: - Rodent, and	TGAI	A	Partially	00129979	Yes 8/	11/90
	ETU	A	No		Yes	5/90
- Non-rodent (Dog)	TGAI	A	No		Yes 9/	11/90
	ETU	A	No		Yes	5/90
83-2 - Oncogenicity - 2 species: - Rat (preferred), and	TGAI	A	Partially	00129979	Yes 8/	11/90
- Mouse (preferred)	TGAI	A	No		Yes	11/90
83-3 - Teratogenicity - 2 species: - Rat	TGAI	A,B,H	No		Yes	12/88
- Rabbit	TGAI	A,B,H	No		Yes	12/88
83-4 - Reproduction - Rat 2-generation	TGAI	A	No		Yes	12/90
	ETU	A	No		Yes	12/90

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use[2] Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.340 - Toxicology - Continued						
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,H	Partially	40091303	Yes 10/	6/88 13/
84-2 - Structural Chromosomal Aberration	TGAI	A,B,H	Yes	00149570 40091301	No	
84-4 - Other Genotoxic Effects	TGAI	A,B,H	Partially	40163901	Yes 11/	9/88
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B,H	Yes	00153352	No	
85-2 - Domestic Animal Safety	Choice		No		No	
85-3 - Dermal Absorption	PAIRA	A,B,H	Partially	00153475	Yes 12/	3/88 14/

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substance determined on a case-by-case basis.

2/ The use patterns are coded are follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; H = Domestic Outdoor

3/ These data have previously been requested in the Comprehensive Data Call In Notice issued April 1987. The time frame for submission of data is the same as required in the April 1987 Data Call In Notice.

4/ This test is required only for compounds which are organophosphate inhibitors of cholinesterase, or related to such inhibitors or metabolites of such inhibitors. Maneb is not an organophosphate, therefore, a study in not required.

5/ This requirement is conditionally waived based on the submission of an acceptable chronic feeding study in the rat.

6/ This study is not required under the existing use patterns. A 21-day dermal study is being required.

7/ Additional information consisting of histopathology data from rats sacrificed after a 13-week recovery period, as well as analytical data (manganese in lung tissue and residues of ETU and/or Maneb in lung tissue) is required.

8/ The 31-month rat feeding study (MRID 129979), with additional information, may satisfy this data requirement. If you elect to submit the additional information, it must be submitted to the Agency within 120 days from your receipt of this document. If this information is submitted and determined to be inadequate or if you do not submit information within that time period, an acceptable study must be submitted to the Agency by 11/90.

9/ Special neurologic observations must be added to this study. The registrant must submit a protocol to the Agency for consideration prior to commencing the study. [Ref.: DeLahunta, A. (1983) Small animal neurologic examination and index of diseases of the nervous system. In Veterinary Neuroanatomy and Clinical Neurology, pp. 365-387. W.B. Saunders, Philadelphia.

10/ Clarification of the percentage of active ingredient in the test substance is required.

11/ The submission of individual data is required to upgrade this study.

12/ Additional data; i.e., submission of the analyses of samples collected during the study (^{14}C-activities in the carcasses) are necessary in order to obtain a more precise measurement of the amount of Maneb absorbed. Additional work may be required, depending on the evaluation of the above-requested analyses, to determine whether, (and if so, at what rate) the Maneb bound to the skin is absorbed after 10 hours, and whether accumulation occurs.

13/ The Agency has received and is currently reviewing additional information.

14/ Registrant has requested a time extension until October 1988.

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test[1] Substance	Use[2] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.390 - Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No		Yes 4/	7/89
132-1 - Soil Dissipation	TEP	A	No		Yes 5/	7/89
133-3 - Dermal Exposure	TEP	A,B	No		No 6/	
133-4 - Inhalation Exposure	TEP	A,B	No		No 6/	
§158.440 - Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A	No		Yes	6 Months
201-1 - Drift Field Evaluation	TEP	A	No		Yes	6 Months

1/ Composition: TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial Food Crop, B = Terrestrial Non-Food Crop.

3/ The foliar dissipation and soil dissipation data requirements were previously required in the Comprehensive Data Call In Notice issued April 1987. The time frame for submission of data is the same as identified in the April 1987 Data Call In Notice.

4/ For each end-use, the registrant is required to propose an acceptable reentry interval based either upon data: (a) on dissipation of reisues (decline curve), on human exposure to those residues, and on toxicity of the residues; or (b) on determination of that time beyond which there are no detectable dislodgeable or inhalable residues remaining in the worker environment.

5/ Soil Dissipation data are required only for uses where workers will be exposed directly to substantial quantities of soil during their work, e.g. for use on potatoes or peanuts if hand harvesting will be performed.

6/ Human-exposure monitoring data may be submitted if the registrant wishes to use the "allowable exposure method" of determining reentry intervals. The data submitted are limited to foliar and soil dissipation studies, human exposure (and reentry intervals) would be estimated from dislodgeable residues as explained in Subdivision K of the Guidelines. If exposure studies are submitted, both dermal exposure and inhalation exposure must be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test[1] Substance	Use[2] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[3]	Time Frame for[4] Submission
§158.490 - Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,H,[E,F][3/]	No		Yes	6/88[18/]
71-2 - Avian Subacute Dietary Toxicity	TGAI	A,B,H,[E,F][3/5/]	Partial[6/]	00104264 00098651[7/]	Yes	6/88[18/]
- Upland Game Bird, and - Waterfowl	ETU	A,B,H	No		Reserved[8/9/]	
71-3 - Wild Mammal Toxicity	TGAI	A,B	No		No	
71-4 - Avian Reproduction	TGAI	A,B	No		Yes[10/]	3/89
- Upland Game Bird, and - Waterfowl	ETU	A,B	No		Reserved[9/11/]	
71-5 - Simulated Field Testing - Mammals, and - Birds	TEP	A,B	No		Reserved[11/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test[1] Substance	Use Pattern[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[3]	Time Frame for[4] Submission
§158.490 - Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity	TGAI	A,B,H,[E,F][3][5]	No		Yes	6/88[18]
	TEP (80%WP 4 lb FC)	A	Partially[12]	97240	Yes[13]	6/88[18]
	ETU	A,B	No		Reserved[9][15]	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,H[E,F][3]	No		Yes	6/88[18]
	TEP (80%WP 4 lb FC)	A	No		Yes[13]	9 Months
	ETU	A	No		Reserved[9][16]	
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A	No		Yes	9/88
	TEP (80%WP 4 lb FC)	A	No		Yes	12 Months
	ETU	A	No		Reserved[9][15]	
- Shrimp	TGAI	A	No		Yes	9/88
	TEP (80%WP 4 lb FC)	A	No		Yes	12 Months
	ETU	A	No		Reserved[9][15]	

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test[1] Substance	Use Pattern[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[3]	Time Frame for Submission[4]
§158.490 - Wildlife and Aquatic Organisms - Continued						
- Oyster	TGAI	A	No		Yes	9/88
	TEP (80%WP 4 lb FC)	A	No		Yes	12 Months
	ETU	A	No		Reserved[9][15]	
72-4 - Fish Early Life Stage, and Invertebrate Life-Cycle - Fish	TGAI	A,B	No		Yes[14]	12/88
	ETU	A,B	No		Reserved[15]	
- Invertebrate (Freshwater & Estuarine)	TGAI	A,B	No		Reserved[16]	
	ETU	A,B	No		Reserved[16]	
72-5 - Fish - Life-Cycle						
Estuarine	TGAI	A	No		Reserved[17]	
Freshwater	TGAI	A	No		Reserved[17]	
72-6 - Aquatic Organism Accumulation (Fish)	TGAI	A	No		Yes	6/88[19]
72-7 - Simulted or Actual Field Testing - Aquatic Organism	TEP	A,B	No		Reserved[15]	

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

§158.490 - Wildlife and Aquatic Organisms - Continued

1/ TGAI = Technical Grade Active Ingredient, TEP = Typical End-Use Product.

2/ A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhoue, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Required to support the manufacturing use product for reformulation into these end-use products.

4/ These data requirements that have specific dates under time frames have been previously requested in the Comprehensive Data Call In Notice issued April 1987. The time frame for submission of these data is the same as required in the April 1987 Data Call In Notice. When number of months are provided, these are new data requirements which must be fulfilled in the number of months specified from the registrants's receipt of this document.

5/ Only one species is required.

6/ A waterfowl study has been provided but does not fulfill the requirements.

7/ Provision of dose mortality data will fulfill requirement.

8/ Pending the results of photolysis and hydrolysis studies, there may be requirements for waterfowl and uplant game bird studies.

9/ ETU is the primary degradate of maneb. The material is water soluable and is persistent in water beyond 4 days.

10/ All outdoor uses permit multiple applications before or during breeding season for birds.

11/ Pending results of avain reproduction studies on technical maneb and environmental fate data such as hydrolysis and photolysis the study could be required to support such uses as apples, corn and cranberries.

12/ Only the requirement for the warmwater fish on an 80WP has been fulfilled.

13/ Required to support cranberry use.

14/ The bluegill LC50 for the 80WP is 1.0 ppm and the estimated environmental concentrations for such sites as apples, cranberries, potatoes, corn, and turf exceen 0.01 x a fish LC50.

15/ Reserved pending results of environmental fate data such as hydrolysis, photolysis and aquatic field dissipation and studies on technical maneb.

Footnotes continued

16/ Reserved pending results of environmental fate data such as hydrolysis and photolysis and the acute aquatic invertebrate study.

17/ May be required to support the cranberry use pending the results of partial chronic studies on technical maneb.

18/ Studies have recently been submitted and are being reviewed.

19/ The Agency is currently reviewing a waiver request for this study.

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test[1] Substance	Use[2] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.540 - Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	EP	A	No		No[4]	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		No[5]	
122-1 - Vegetative Vigor	TGAI	A	No		No[5]	
122-2 - Aquatic Plant Growth	TGAI	A	No		Yes	1/88[8]
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		No[5]	
123-1 - Vegetative Vigor	TGAI	A	No		No[5]	
123-2 - Aquatic Plant Growth	TGAI	A	No		Reserved[6]	
TIER III						
124-1 - Terrestrial Field	TEP	A	No		No[5]	
124-2 - Aquatic Field	TEP	A	No		Reserved[7]	

§158.540 - Plant Protection - Continued

1/ TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, food crop (cranberries).

3/ This data has previously been requested in the Comprehensive Data Call In Notice issued April 1987. The time frame for submission of data is the same as required in the April 1987 Data Call In Notice.

4/ Whether data are required is determined on a case-by-case basis, where phytotoxicity issues may be involved.

5/ Use in aquatic sites does not require submission of terrestrial phytotoxicity data.

6/ Reserved pending results of Tier I.

7/ Reserved pending results of Tier II.

8/ Basic Producer proposed to delete cranberries from their label and this data requirement would not apply to them. However, unless the formulators have removed the cranberry use from their labels, this data requirement applies.

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Pattern[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.590 - Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B	Yes	00036935	No	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	No		No[3]	
141-4 - Honey bee subacute feeding study	(Reserved)[4]					
141-5 - Field testing for pollinators	TEP	A,B	No		No[3]	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved)[5]					
142-1 - Aquatic insect life-cycle study	(Reserved)[5]					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)[5]					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)[5]					

TABLE A
GENERIC DATA REQUIREMENTS FOR MANEB

Data Requirement	Test Substance[1]	Use Pattern[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.590 - Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B	Yes	00036935	No	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	No		No[3/]	
141-4 - Honey bee subacute feeding study	(Reserved)[4/]					
141-5 - Field testing for pollinators	TEP	A,B	No		No[3/]	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved)[5/]					
142-1 - Aquatic insect life-cycle study	(Reserved)[5/]					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)[5/]					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)[5/]					

§158.590 - Nontarget Insect - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood.

3/ As data from the acute contact study show low toxicity to honey bees, no further testing is required.

4/ Reserved pending development of test methodology.

5/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING MANEB

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
Part 158 Subpart C - Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	Yes	desk reference	No	
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	Partially	40553401 00148115 00164487 00096454	Yes[3]	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	Partially	40553401 00164487	Yes[4]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	Partially	00148115 40553402 00164487	Yes[5]	12 Months[16]
62-2 - Certification of Limits	MP	All	Partially	40553402 00164487 00148115	Yes[6]	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	Partially	40553401 00148115 00164487 00096318 00096454	Yes[7]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	Partially	40553403	Yes[8]	6 Months
63-3 - Physical State	MP	All	Partially	40553403	Yes[8]	6 Months
63-4 - Odor	MP	All	partially	40553403	Yes[8]	6 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING MANEB

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
Part 158 Subpart C - Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	Yes	desk reference	No	
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	Partially	40553401 00148115 00164487 00096454	Yes[3]	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	Partially	40553401 00164487	Yes[4]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	Partially	00148115 40553402 00164487	Yes[5]	12 Months[16]
62-2 - Certification of Limits	MP	All	Partially	40553402 00164487 00148115	Yes[6]	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	Partially	40553401 00148115 00164487 00096318 00096454	Yes[7]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	Partially	40553403	Yes[8]	6 Months
63-3 - Physical State	MP	All	Partially	40553403	Yes[8]	6 Months
63-4 - Odor	MP	All	partially	40553403	Yes[8]	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING MANEB

Data Requirement	Test Substance[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
Part 158						
Subpart C - Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes 8/	6 Months
63-12 - pH	MP	All	Partially	40553403	Yes 9/ 10/	6 Months
63-14 - Oxidizing or Reducing Action	MP	All	Partially	40553403	Yes 11/	6 Months
63-15 - Flammability	MP	All	Partially	40553403	Yes 12/	6 Months
63-16 - Explodability	MP	All	No	N/A	Yes 13/	6 Months
63-17 - Storage Stability	MP	All	Partially	00164057 00164487	Yes 8/	15 Months
63-18 - Viscosity	MP		N/A	N/A	No 14/	
63-19 - Miscibility	MP		N/A	N/A	No 15/	
63-20 - Corrosion Characteristics	MP	All	Partially	40553403	Yes 9/	15 Months
Other Requirements:						
64- 1 - Submittal of samples	N/A	N/A	N/A	N/A	No	

1/ Test Substance: MP = Manufacturing-Use Product.

2/ Data must be submitted within the time frame indicated from receipt of this package.

3/ For all formulation intermediates with the exception of the Pennwalt 86% FI (EPA Reg. No. 4581-355), complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the fianl product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

4/ A detailed discussion of all impurities that are or may be present at $\geq$0.1% based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production including post-production reactions among components of the product and its packaging must be submitted for all manufacturing-use products with the exception of the Pennwalt 86% FI, EPA Reg. No. 4581-355.

5/ Five or more representative samples of each manufacturing-use product must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. The active ingredient in these samples must be analyzed for maneb *per se* using a method capable of differentiating maneb from interfering CS_2-liberating impurities must be quantified. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

6/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity associated with the active ingredient present at $\geq$0.1% (w/w) and each "toxicologically significant" impurity associated with the active ingredient present at $<$0.1% (w/w) must be provided and certified for each manufacturing-use product. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Maneb *per se* must be analyzed by a method capable of differentiating maneb from interfering CS_2-liberating impurities. An explanation of how each certified limit was established must be provided (e.g. sample analysis using *validated* analytical procedures, qualitative estimates based on amounts of ingredients used, etc.).

7/ Analytical methods must be provided for each product to determine the active ingredient and each impurity for which a certified limit is required. The analytical method for the active ingredient must be able to differentiate maneb *per se* from interfering CS_2-liberating impurities. For CS_2-liberating impurities, HPLC methodology may be most appropriate for achieving the required specificity. All methods must be accompanied by validation studies indicating accuracy and precision. These methods must be suitable for *enforcement* of certified limits.

8/ Physicochemical characteristics (color, physical state, odor, density, and storage stability) as required in 40 CFR 158 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted for each formulation intermediate with the exception of the 86% FI (EPA Reg. No. 4581-355).

9/ Data on pH and corrosiveness are required for each formulation intermediate.

10/ Data required if the test substance is dispersible in water.

11/ With the exception of the 86% FI (EPA Reg. No. 4581-355), data are required for each formulation intermediate product, if the product contains oxidizing or reducing agents.

12/ With the exception of the 86% FI (EPA Reg. No. 4581-355), data are required for each formulation intermediate product, if the product contains combustible liquids.

13/ With the exception of the 86% FI (EPA Reg. No. 4581-355), data are required for each formulation intermediate product if the product is potentially explosive.

14/ Data required if the product is a liquid.

15/ Data required if the product is a liquid and is to be diluted with petroleum solvents.

16/ All nitrosamines must be identified and quantified in six samples; two samples of each must be analyzed shortly after production and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used.

APPENDIX II

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR Part 152, Subpart I. You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

Chapter 1--Environmental Protection Agency

§156.10 Labeling Requirements
previously cited as §162.10

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ****" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or

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damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification.
(A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

APPENDIX III

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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MRID	CITATION
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00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)
00040149	Gordon, ?; et al. (1967) [Without title]. Journal of the Association of Official Analytical Chemists 50(5):1103-1108. (Incomplete article dealing with Ethylenebisdithiocarbamate residues; also in unpublished submission received Apr 3, 1972 under 2F1258; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 095544-C)
00041799	Lowen, W.K. (1953) Analysis of Manganese ethylenebisdithiocarbamate compositions and residues. Journal of the Association of Official Agricultural Chemists 36(2):484-493. (Also in unpublished submission received Jun 15, 1955 under PP0021; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL: 090020-D)
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00153475	Puhl, R. (1985) Dermal Absorption of Radiolabelled Maneb in Male Rats: Final Report: Study No. 6181-100. Unpublished study prepared by Hazleton Laboratories America, Inc. 49 p.
00159847	Weete, J. (1986) Report to the Maneb Task Force on Metabolism of [Carbon 14] Maneb in Potato Plants. Unpublished study prepared by Auburn Univ., Dept of Botany, Plant Pathology, and Microbiology. 40 p.
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00161800	BASF Corp. (1986) Maneb Technical: [Product Chemistry]. Unpublished study. 64 p.
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MRID CITATION

40553402 Kool, P. (1988) Maneb Technical: Product Chemistry: Project ID: MANEB62. Unpublished compilation prepared by Pennwalt Holland B.V. 41 p.

40553403 Kool, P. (1988) Maneb Technical: Product Chemistry: MANEB63. Unpublished compilation prepared by Pennwalt Holland B.V. 10 p.

APPENDIX IV

Form Approved. OMB No. 2070-0057. Approval expires 11-30-89.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________________

Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ______________ concerning a requirement for submission of "generic" data on the active ingredient ______________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated __________________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________ and their registration number(s) is/are ____________________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature

ated: ____________________ ______________________________
(Typed)

orm 8570-27

OMB Approval No.
2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No. ____________________ Date ____________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Sec. 158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

OMB Approval No.
2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No. ______________________ Date ______________________

Guidance Document for ______________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Sec. 158.120 PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

Form Approved. OMB No. 2070-0057. Expires 11-30-89.

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)